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APPLICATION TEAM PROGRAM

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PREFACE

This report covers the medically related activities of the NASA Application Team Program at the Research Triangle Institute between September 1, 1972, and August 31, 1973, performed in accomplishing NASA Contract NASW-2459. This work was performed in the Center for Technology Applications of the Research Triangle Institute under the technical direction of Dr. J. N. Brown, Director. Full-time members of the Team who participated in the project are Dr. F. T. Wooten, Director of the Application Team; Mr. Ernest Harrison, Jr.; Dr. E. W. Page; Mr. R. W. Scearce; and Ms. Jackie Manning. Assistance from other members of the RTI staff was obtained as needed.

Medical consultants who contributed significantly to the project are Dr. E. A. Johnson, Duke University Medical Center, Durham, North Carolina; Dr. George S. Malindzak, Jr., Bowman Gray School of Medicine, Wake Forest University, Winston-Salem, North Carolina; Mr. William Z. Penland, National Cancer Institute, Bethesda, Maryland; Professor Hal C. Becker, Tulane University School of Medicine, New Orleans, Louisiana; Dr. Jacob Kline, University of Miami School of Medicine, Miami, Florida; and Mr. Edward Wallerstein, Mount Sinai Medical Center, New York.

For the convenience of the reader, the names and addresses of the sources of certain commercial products are included in this report. This listing does not constitute an endorsement by either the National Aeronautics and Space Administration or the Research Triangle Institute.

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ABSTRACT

This report presents the results of the medically related activities of the NASA Application Team Program at the Research Triangle Institute. This experimental program in technology application was supported by NASA Contract No. NASW-2459 for the reporting period September 1, 1972, to August 31, 1973. The RTI Team is a multidisciplinary team of scientists and engineers acting as an information and technology interface between NASA and individuals, institutions, and agencies involved in biomedical research and clinical medicine. During the reporting period, participants in the Application Team Program included Dr. J. N. Brown, Jr., Electrical Engineer; Dr. F. T. Wooten, Electrical Engineer; Mr. Ernest Harrison, Materials Scientist; Dr. E. W. Page, Electrical Engineer; Mr. R. W. Scearce, Biomedical Engineer; and Ms. Jackie Manning. In addition, the Team draws upon the capabilities of other members of the RTI staff as needed.

Fifteen medical organizations are presently participating in the RTI Application Team Program: Bowman Gray School of Medicine, Wake Forest University, Winston-Salem, North Carolina; Duke University Medical Center, Durham, North Carolina; Emory University School of Medicine, Atlanta, Georgia; Illinois Pediatric Institute, Chicago, Illinois; Medical University of South Carolina, Charleston, South Carolina; Mount Sinai Medical Center, New York, New York; National Cancer Institute, Bethesda, Maryland; National Heart and Lung Institute, Bethesda, Maryland; National Institute of Environmental Health Sciences, Research Triangle Park, North Carolina; Ochsner Clinic and Foundation, New Orleans, Louisiana; Tulane University School of Medicine, New Orleans, Louisiana; University of Miami School of Medicine, Miami, Florida; University of North Carolina Dental School and Dental Research Center, Chapel Hill, North Carolina; and Virginia Department of Vocational Rehabilitation, Fishersville, Virginia.

The accomplishments of the Research Triangle Institute Application Team during the reporting period are as follows: The Team has identified 39 new problems for investigation, has accomplished 7 technology applications, 4 potential technology applications, 2 impacts, has closed 38 old problems, and on August 31, 1973, has a total of 59 problems under active investigation.

1.0 PROGRAM PHILOSOPHY AND METHODOLOGY

1.1 Introductory Comments

The National Aeronautics and Space Administration (NASA) has been a leader and innovator in the establishment, operation, and assessment of technology transfer programs since that agency was established by the Space Act of 1958. Through its Tech Brief, Special Publication, Technology Survey, and Regional Dissemination Center programs, NASA has been successful in transferring the results of aerospace research to an impressive number of nonaerospace applications.

In 1966, NASA established a program using an active and directed methodology. In this program, Application Teams were established under contract to the NASA Technology Utilization Office. The Application Team methodology is active in that specific problems are identified and specified through direct contact with potential users of aerospace technology. The process is directed in that Teams interact only with potential users who are involved in reaching selected national goals. Three Teams concentrate in the biomedical area while others work in such fields as air pollution control, water pollution control, transportation, mine safety, and urban problems. The three Teams specializing in biomedicine have been established at the following institutions:

Research Triangle Institute
Post Office Box 12194
Research Triangle Park, North Carolina 27709

Southwest Research Institute
8500 Culebra Road
San Antonio, Texas 78228

Stanford University School of Medicine
701 Welch Road
Palo Alto, California 94304

This report covers the accomplishments and activities of the Team located at the Research Triangle Institute for the period September 1, 1972, to August 31, 1973. In the remainder of Section 1.0, Team objectives and methodology are presented.

1.2 Application Team Program

The NASA Application Team Program specifically seeks to achieve the following goals:

- (a) The identification of relevant aerospace technology that can solve major medical problems;
- (b) The utilization of the identified technology in order to actually solve the existing medical problems; and
- (c) The motivation of members of the industrial community to manufacture technology resulting from this program in order that widest possible use of the technology can be achieved.

Basically, the Team acts as an active interface between medical investigators and the body of scientific and technical knowledge that has resulted from this Nation's aerospace research program. The Team attempts to carefully define the technological problems facing the medical community and to identify the relevant aerospace technology that can solve those problems. The problems are those being encountered in medical research programs in major medical schools and in the National Institutes of Health. The Team actively engages in the identification of these problems through direct contacts with the medical research staffs; the identification and specification of the medical problems is then followed by search for technology that can be utilized in solution of the problem.

Generally, technology relevant to specific problems is identified through three approaches: (1) manual and computer searching of the aerospace information bank created by NASA as part of its R&D effort, (2) direct contact with the engineering and scientific staff at NASA Field Centers, and (3) circulation of concise problem statements to a large number of NASA scientists and engineers. Technology representing potential solutions to problems is channeled through the Team to the problem originator for evaluation and implementation as a solution to his problem. Alternatively, and with increasing frequency, the Team establishes a contact between the problem originator and NASA Field Center personnel, and the transfer of information between NASA and the medical field becomes more direct.

Assistance to the problem originator in implementing solutions to problems is an important part of the Application Team Program. This assistance may take any one of a number of different forms. Direct assistance to the problem originator in his efforts to implement a solution is frequently involved. During this reporting period, NASA's

Technology Utilization Division has utilized reengineering or adaptive engineering facilities of various NASA centers in those cases where feasibility had to be demonstrated. The Teams are responsible for identifying the NASA technology that is potentially a solution to a specific problem and for specifying the changes required in this technology. The adaptive engineering activity allows the Teams to demonstrate that the technology is in fact a solution to the problem and allows the problem originator to make use of the NASA technology in his research that might otherwise be impossible.

The successful transfer of information on aerospace technology to an individual or group in the medical field followed by successful implementation of the technology with resulting benefits to the accomplishment of some medical objective is called a "technology application." Also included in the definition of technology application is the constraint that the medical application and objective involved in the technology application be different from the aerospace application and objective for which the technology was originally developed. Thus, the accomplishment of technology applications is indeed a difficult and long-term objective. This objective should be distinguished from that involved in a program to enhance the diffusion or broad utilization of demonstrated applications of technology. The transfer of technology involves crossing what may be thought of as an "application or objective barrier," and it involves complete evaluation of the new application; diffusion involves neither of these requirements.

A specific methodology is applied by the Team in its efforts to effect applications of aerospace-related technology. This methodology is discussed in the following section.

1.3 Methodology

The methodology used by the Team consists of five basic steps: problem definition, identification of relevant technology, evaluation of relevant technology, utilization of technology, and documentation. This methodology can be better understood, however, if it is separated into the steps shown in Figure 1. These steps are described in the following paragraphs.

Problem Screening - Effective problem screening is at least as important to the success of the Application Team Program as any of the operational steps identified in Figure 1. Analysis of the RTI Team's accomplishments in the early days of the program indicates clearly that a very significant fraction of the problems that were investigated unsuccessfully could have been rejected very early in discussions with problem originators. Problem selection criteria have since been developed with the objective being to increase the probability that a technology application can be accomplished for those problems accepted by the Team. At the present the following criteria are being applied:

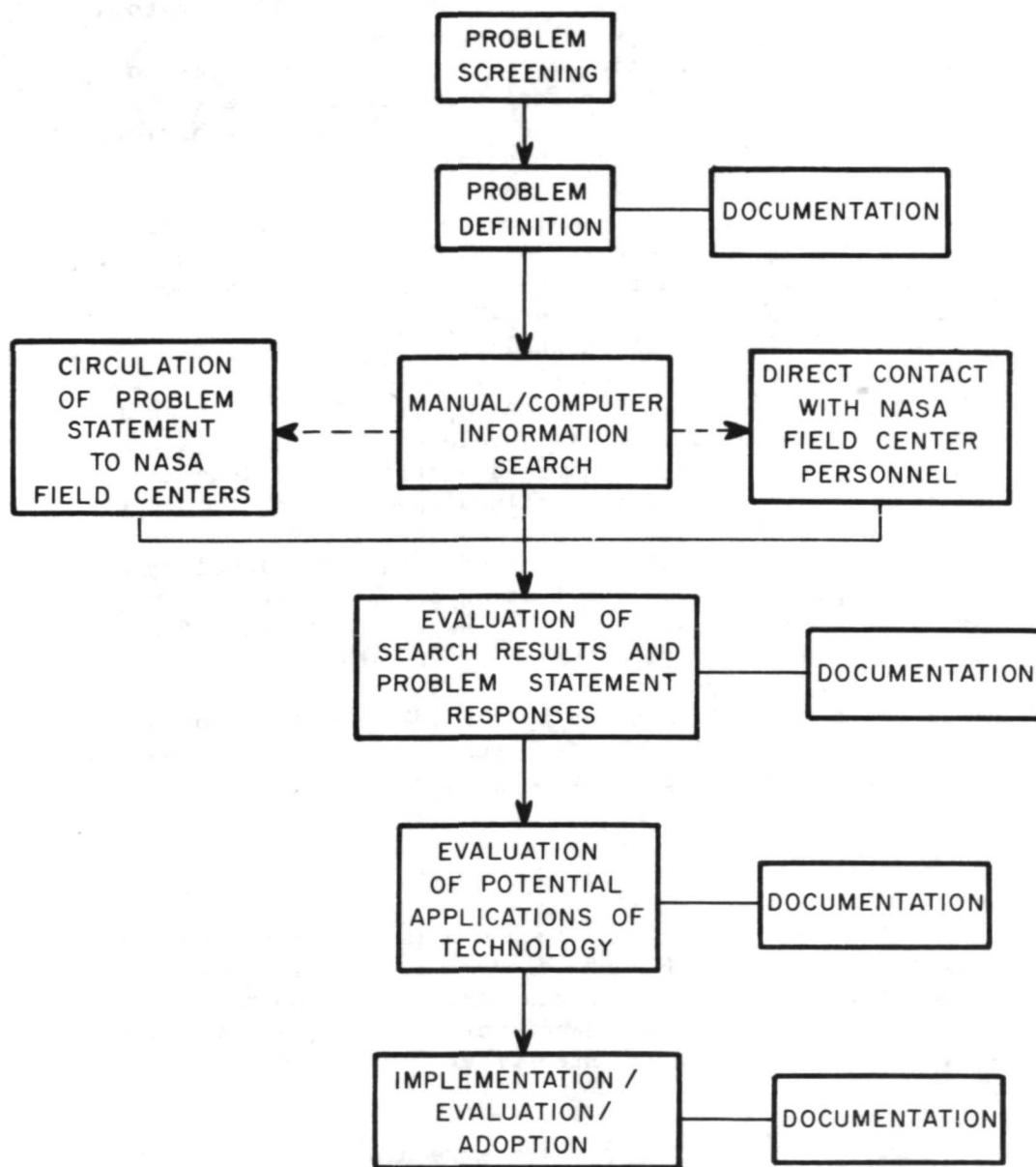


Figure 1. Flow Chart of Application Team Transfer Methodology.

- (a) Solving the problem would enhance medical diagnosis, treatment, or patient care to the extent that implementation and adoption would be rapid.

OR

- (b) The problem has been encountered in an ongoing research program and is impeding progress of that program.

OR

- (c) Either some unique characteristics of the problem or the problem originator indicates that investigating the problem will enhance the overall Team program.

AND

- (d) Solving the problem is given high priority by the problem originator.

AND

- (e) The problem is one of *at most* two being investigated with an individual problem originator. (This is violated only in the case of large group efforts.)

Problems that do not satisfy these criteria are rejected. Problems may also be rejected following partial completion of the next step, problem definition.

Problem Definition - The objective of this step is to define precisely and accurately the characteristics of the technology required to solve a problem. In many cases, following the characterization of required technology, it is found that the problem should be rejected or closed for any of a number of reasons. These reasons include, as examples, the following: (1) the problem can be solved using commercially available equipment; (2) the problem cannot be solved, so that an entirely different approach is indicated; (3) the real problem is medical and not technical in nature; and (4) the requirements cannot be specified because insufficient information exists on the objective involved.

The end result of problem definition is the preparation of a problem statement. This statement, to be complete, must contain (1) a complete characterization of what is required to solve the problem, and (2) the related medical problem or objective and the benefits to be realized by solving the problem.

Identification of Relevant Aerospace Technology - Aerospace technology that may be relevant to the solution of a problem is identified by

three approaches. First, a manual or computer search is made of the aerospace information bank. These searches are made at one of NASA's six Regional Dissemination Centers (RDC). The RDC used by the RTI Team is the North Carolina Science and Technology Research Center (NCSTRC) located in Research Triangle Park, North Carolina. In addition, searches are made utilizing the NASA Scientific and Technical Information Facility in College Park, Maryland. The information that can be assessed through the information bank consists of approximately 700,000 documents, articles, and translations that have been abstracted in the Scientific and Technical Aerospace Reports (STAR) and the International Aerospace Abstracts (IAA). Second, the Team contacts individuals at the Field Centers directly without circulating problem statements. This is done when a Team member can identify a relatively few individuals at the Field Centers who are likely to have a good overview of all work being done that is related to the requirements of a specific problem. Third, problem statements are circulated to engineers and scientists at NASA Field Centers who may be able to identify relevant technology and suggest possible solutions to problems. These statements are circulated in a highly selective manner with the distribution being determined by the Team, Technology Utilization Officers (TUE) at the NASA Field Centers, and other individuals at the Field Centers.

Evaluation - All potentially relevant technology identified in the preceding step is evaluated by the Team to determine whether a potential solution to a specific problem has been found. Those items of technology that represent potential solutions to problems are presented to problem originators along with available supporting data and information. Any required reengineering and details of implementing the potential solutions are discussed with the problem originator.

The problem originator must then evaluate potential solutions. His decision to implement a proposed solution will depend upon a number of factors: (1) his assessment of the validity of the proposed potential solution, (2) the cost of implementing the potential solution, (3) the potential benefits to be gained, etc. The Team may be asked to supply additional information and technical details in this evaluation.

Implementation, Final Evaluation, Adoption - The final step in the technology application process is the implementation and the experimental evaluation of potential solutions. This critical phase must occur in order for a technology application to be complete. The team is available for assistance in this step when required, and attempts to identify the resources necessary to meet the implementation requirements. In many cases the actual implementation can be carried out by the problem originator and his staff. In some cases, however, skills not immediately available to the problem originator are required for implementation and, in these cases, some other resource is utilized. This may require the use of a NASA capability at one of the Field Centers or at a NASA contractor. In other cases the implementation may be carried out by an industrial concern under contract to the problem originator. In general, the team attempts to determine the most appropriate means of implementation and to make recommendations to the problem originator as required.

Documentation - Documentation is an integral part of the Team methodology; it is involved at most steps in the process, as indicated in Figure 1. Documentation allows analysis of the technology application process and assessment of the program in general. At present, the Teams report on a weekly, monthly, and semiannual schedule. Effective communication is required between Teams, potential problem originators, and other individuals who are in a position to make use of information resulting from technology applications accomplished by the Teams.

1.4 Application Team Composition and Participating Medical Institutions

The RTI Team is a multidisciplinary group of engineers and scientists. The educational backgrounds of the group are in physics and electrical engineering; their experience includes industry, education, and research at both basic and applied levels. The individuals who have participated in the Application Team Program during this reporting period are:

Name	Background	Responsibility
Dr. J. N. Brown, Jr.	Electrical Engineer	Laboratory Supervisor
Dr. F. T. Wooten	Electrical Engineer	Team Director
Mr. E. Harrison, Jr.	Materials Scientist	Solution Specialist
Dr. E. W. Page	Electrical Engineer	Solution Specialist
Mr. R. W. Scearce	Biomedical Engineer	Solution Specialist
Ms. Jackie Manning	Secretary	Documentation

The experience and special capabilities of other individuals at RTI--particularly in the Engineering and Environmental Sciences Division--are frequently used as needed in the Application Team Program.

At present, 15 medical institutions are participating in the RTI Application Team Program. These institutions are as follows:

Bowman Gray School of Medicine, Wake Forest University,
Winston-Salem, North Carolina;

Duke University Medical Center, Durham, North Carolina;
(Including Veterans Administration Hospital, Durham, North
Carolina);

Emory University School of Medicine, Atlanta, Georgia;

Illinois Pediatric Institute, Chicago, Illinois;

Medical University of South Carolina, Charleston, South Carolina;

Mount Sinai Medical Center, New York, New York

National Cancer Institute, Bethesda, Maryland;

National Heart and Lung Institute, Bethesda, Maryland;

National Institute of Environmental Health Sciences, Research
Triangle Park, North Carolina;

Ochsner Clinic and Foundation, New Orleans, Louisiana;
Tulane University School of Medicine, New Orleans, Louisiana;
University of Miami School of Medicine, Miami, Florida;
(Including Veterans Administration Hospital, Miami, Florida);
University of North Carolina Dental School and Dental Research
Center, Chapel Hill, North Carolina;
University of North Carolina School of Medicine, Chapel Hill,
North Carolina;
Virginia Department of Vocational Rehabilitation, Fishersville,
Virginia.

Figure 2 shows the geographical distribution of the RTI Application Team user institutions as well as the location of the major NASA resources.

The RTI Team is assisted at various stages of the technology application process by consultants who are on the medical staffs at participating institutions. These consultants or communicators coordinate Team activities at their institutions and assist Team members primarily in problem definition and evaluation of potential solutions. At present, the following individuals are consultants to the RTI Team.

<i>Name</i>	<i>Specialty</i>
Dr. E. A. Johnson Duke University Medical Center	Cardiac Physiology
Dr. George S. Malindzak, Jr. Bowman Gray School of Medicine, Wake Forest University	Physiology
Professor Hal C. Becker Tulane University School of Medicine	Radiology
Mr. William Z. Penland National Cancer Institute	Engineering
Dr. Jacob Kline University of Miami School of Medicine	Engineering
Mr. Edward Wallerstein Mount Sinai Medical Center	Engineering

Problems at each institution are coded by a letter and number symbol (e.g., DU-49); the coding for each institution or special problem area is as follows:

CP - Computer software-type problem
DU - Duke University Medical Center

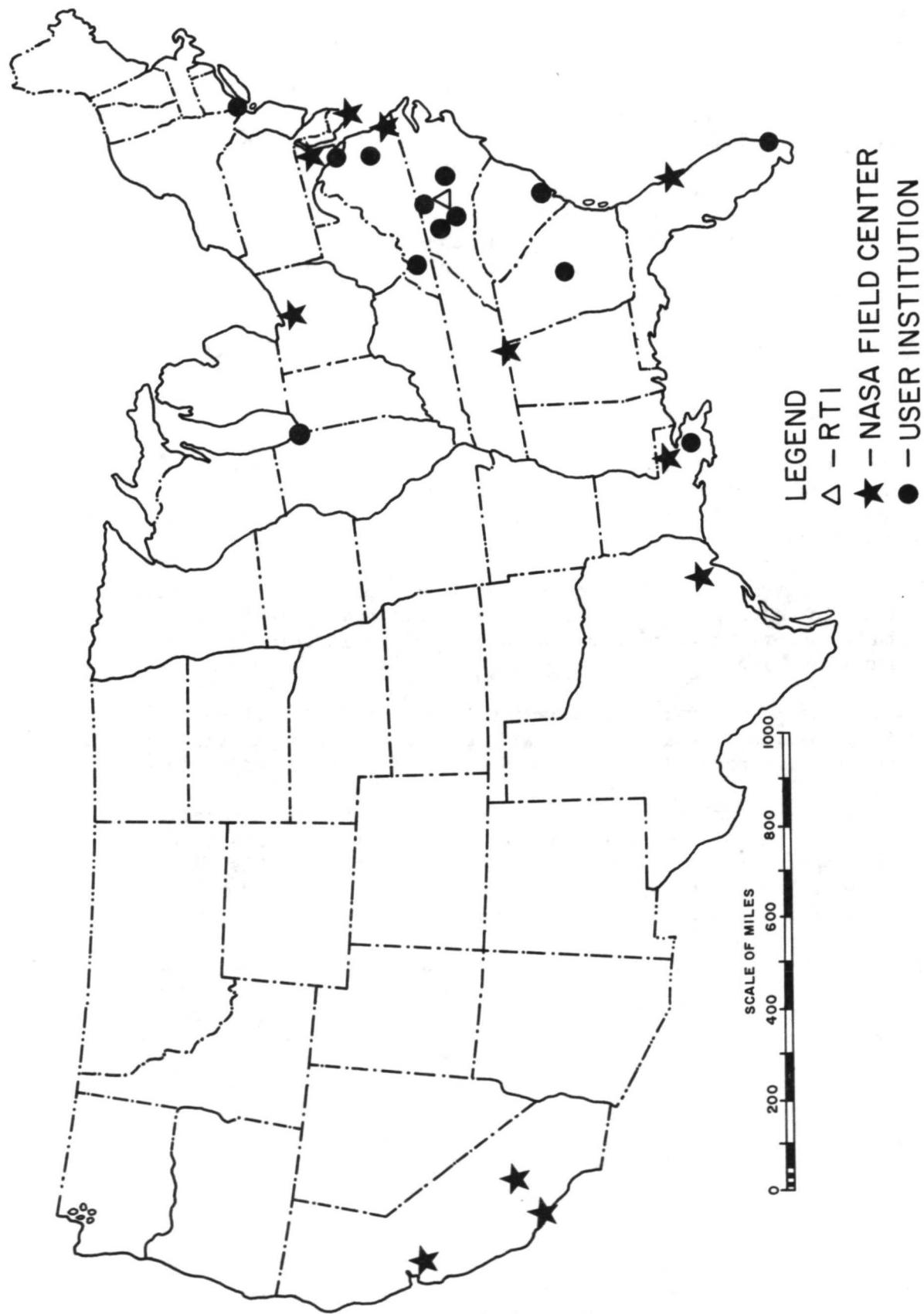


Figure 2. Team Activity Centers in the United States

EU - Emory University School of Medicine
IPI - Illinois Pediatric Institute
MISC - Miscellaneous
MS - Mount Sinai Medical Center
MUSC - Medical University of South Carolina
NCI - National Cancer Institute
NEHSC - National Institute of Environmental Health Sciences
NHLI - National Heart and Lung Institute
OF - Ochsner Clinic and Foundation
TU - Tulane University School of Medicine
UNC - University of North Carolina School of Medicine
UNCD - University of North Carolina Dental School and
Dental Research Center
VAM - University of Miami School of Medicine
WF - Bowman Gray School of Medicine, Wake Forest University

1.5 Definition of Terms

In the Application Team Program, a number of terms have evolved that describe the elements and processes in this program. Because of their number and unfamiliarity to many readers, these terms are listed and defined in this section for reference.

Problem Originator or Researcher - An individual actively involved in an effort to reach a specific objective in biology or medicine and faced with a specific technological problem that is impeding progress toward that objective.

Participating Institution - A medically oriented educational institution, hospital, medical center, or government agency having as one of its organization objectives the improvement of medical health care.

Consultant - A member of the biomedical staff at a participating user institution who has committed a portion of his activities to assist the Team in identifying appropriate problem originators at his institution, in understanding and specifying problems in biology and medicine, and in evaluating technological solutions to problems.

Application Team (Team) - A multidisciplinary group of engineers and scientists engaged in problem-solving activities in medicine with the specific objective of effecting the transfer of aerospace technology to solve problems in medicine. The methodology used by the Team involves (1) problem selection, definition, and specification; (2) identification of potential solutions to problems by manual and computer information searching, circulation of problem statements to NASA Field Centers, and contacts with NASA engineers and scientists; (3) evaluation of potential solutions; (4) implementation and adoption by problem originators of aerospace technology as solutions or partial solutions to medical problems; and (5) documentation.

Problem - A specific and definable technological requirement that cannot be satisfied by commercially available equipment or by application of information available to the problem originator through routinely used information channels.

Problem Statement - This is a concise, written statement of a problem used for communicating (1) sufficient details to allow a computer search to be performed by the information search specialists, and (2) sufficient information to enable NASA engineers and scientists to consider possible solutions to the problem.

Computer Information Search - This is a computerized information search of the aerospace information bank established by NASA and made available through six Regional Dissemination Centers in the United States. This information bank consists of the approximately 700,000 documents that have been indexed and abstracted in the Scientific and Technical Aerospace Reports (STAR) and International Aerospace Abstracts (IAA).

Impact - Information is given to a problem originator with the result that he changes his activities in a way that enhances his progress toward a medical objective. An impact is thus analogous to a technology application except that one or more of the requirements for a technology application are not satisfied.

Potential Technology Application - The search for NASA technology by the application team leads to the identification of relevant technology that offers strong potential for solving the particular problem. A potential technology application occurs when the Team and the problem originator agree on the applicability of the specific NASA technology to the particular problem and when a reasonable plan for achieving implementation exists.

Technology Application - The key factor that permits a potential technology application to become a technology application is implementation. A technology application occurs when aerospace technology is implemented to solve a problem different from the one for which the technology was originally developed.

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2.0 TECHNOLOGY APPLICATIONS, POTENTIAL TECHNOLOGY APPLICATIONS, AND IMPACTS

2.1 Technology Applications

During the reporting period, seven applications of aerospace technology were accomplished and are discussed in the following summaries:

PROBLEM TU-3 *Lung Sound Detection*

A technique developed for aerospace vibration and engine-sound analysis has been successfully applied in the analysis of respiratory disease in children.

The major cause of illness in children from infancy through adolescence is respiratory disease of which the more serious forms include asthma, cystic fibrosis, and bronchitis. Significant research is being conducted both in the causes and cures of respiratory diseases and in better methods of diagnosis of the diseases. This problem is devoted to finding a method of improved diagnosis that will improve the treatment of respiratory diseases.

The respiratory system consists of the lungs and the system of tubes or ducts that feed air into the lungs. Air proceeds from the nose and mouth through the trachea which is the central air duct. From this central tube, two branches diverge that eventually subdivide still further into smaller tubes called bronchial tubes. Each bronchial tube feeds air into and out of a section of the lung, and each tube has a symmetrical counterpart in the other lung.

One useful and simple method to determine whether a portion of the lung is performing properly is to listen to the sounds made by airflow. Usually this is done with a stethoscope, but only one section of the lung can be heard at a time. To compare sections of the lung, it would be useful to be able to compare the sounds generated by a section of the lung with the sounds generated by the symmetrical counterpart in the other lung.

The basic problem is to detect the sounds from two sections of the chest wall by microphones and to display the sounds graphically. Comparison must be made on the amplitude, frequency, and time interval between appearance of the two sounds.

The frequencies of interest are 50-10,000 Hertz. Breathing rates normally are 25 breaths/minute although a range of 12 to 80 occur. The amplitude of the sounds of interest is not known. Measurements are made on children from infancy to adolescence in a hospital clinic.

In the basic description of the problem, the problem originator desired simply a strip chart recorder and microphone combination. However, the Team advised him that far more information could be gained by using spectral analysis such as that used in analyzing aircraft engines. One difficulty in spectral analysis is that real time spectral analysis is required because of the rapidly changing information in lung sound. Thus, a simple scanning-filter spectral analysis technique was insufficient because of the time response required. A computer search of the NASA document file revealed that NASA had done considerable work in spectral analysis--particularly as pertains to aircraft engines analysis and vibration analysis for vibration testing of spacecraft. The Team proposed to the physician a system (See Figure 3) composed of a microphone, amplifier, and envelope detector which could be fed to a dual-channel strip chart recorder. This dual-channel system would allow time delay measurement for respiratory sounds between similar lobes. In addition, the output of the amplifier could be fed into a spectral analyzer similar to that used in aerospace applications.

The problem originator discussed a joint investigation with the NASA contractor who supplies the spectral analysis equipment. The contractor agreed to furnish the equipment at a fraction of the normal cost: in return, the problem originator provided the medical consultation necessary to develop this new product.

The system was assembled and has been used in a clinical environment for 2 years. A typical analysis of pulmonary sounds is shown in Figures 4 and 5. The results have shown that the frequency range of pulmonary sounds are much higher than had been originally reported. In addition, it was shown that a diseased lung and a normal lung exhibited different spectral analysis patterns for the pulmonary sound. The results of this technology application were presented at the Conference on Engineering and Medicine in Biology, held October 1-5, 1972, in Miami.

The Team feels that this technology application has significance in several areas of pulmonary medicine. First, it is clear that the technique is useful as a diagnostic technique, in order to obtain data not available with a stethoscope. In addition, the technique allows the storage of pulmonary sound data in a convenient mode (photograph) and thus allows a convenient means to evaluate the effects of therapy. The technique also has significance as a teaching function by helping medical students learn more about the nature of pulmonary sounds. In addition, the technique offers the potential for learning more about the basic nature of pulmonary physiology.

This research project is continuing at the Tulane University School of Medicine and future research will determine the breadth of application of the technique in clinical medicine. The availability of commercial equipment for this task will enhance the spread of the use of this new technique.

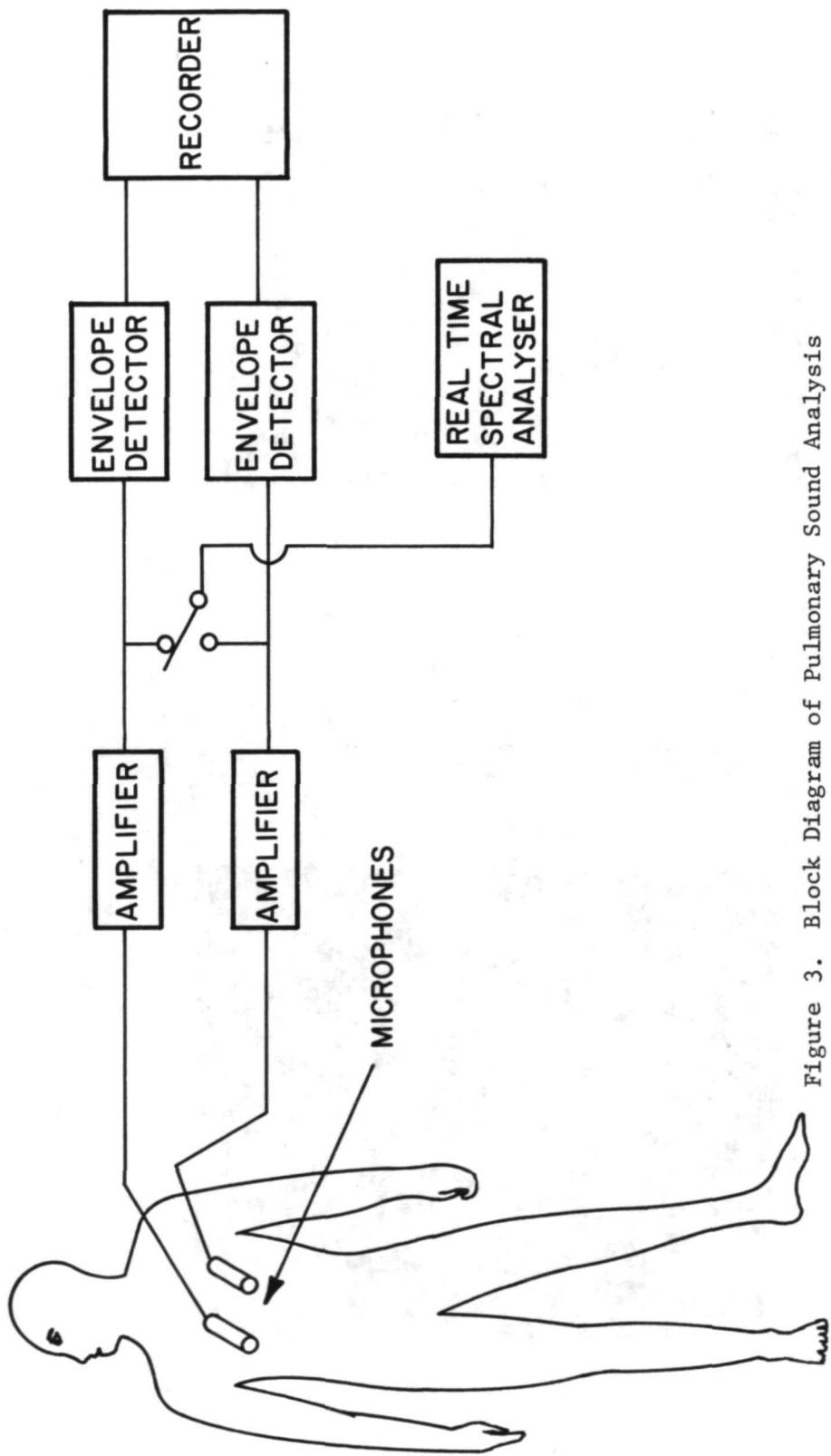


Figure 3. Block Diagram of Pulmonary Sound Analysis System.

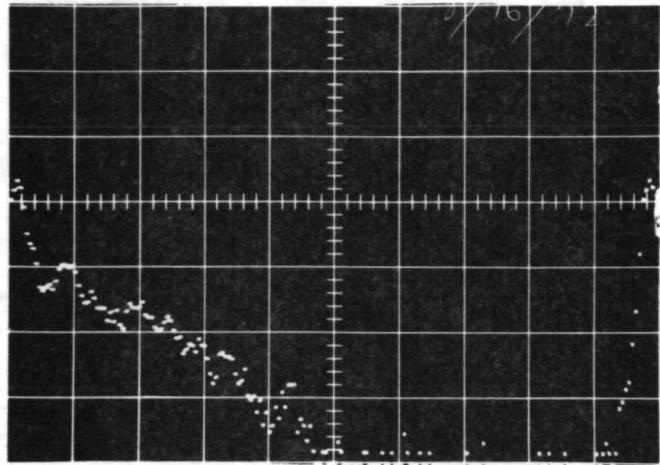


Figure 4. Spectral Analysis of Normal Pulmonary Sound

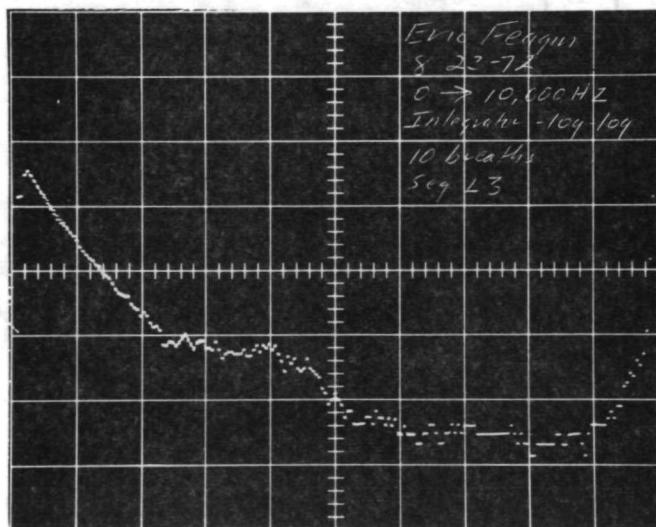


Figure 5. Spectral Analysis of Pulmonary Sounds of Patient with Cystic Fibrosis

PROBLEM MISC-27 *Improved Cushioning Material for Protective Helmets*

A material developed by NASA for spacecraft cushions has been used to reduce injury to epileptic patients when they fall.

Two teenage boys at the Western Carolina Center of the North Carolina Department of Mental Health suffer from grand mal epileptic seizures. Both of these boys are normal in other respects and engage in many of the activities of normal boys, but as a result of their activity, the grand mal seizures are a constant threat of injury. Typically, if the patient is standing during a grand mal seizure, he will extend his legs, rigidize the body, and fall in some direction depending upon the particular stage of balance at the moment of the seizure. Although some patients appear to be predisposed to falling in a particular direction, all possible directions of falling are generally experienced.

When one of these patients falls, the part most likely to experience severe injury is the head. This is true because the patient generally is rigidized and falls much as a rigid body so that the head is accelerated over a significant distance. A tremendous force is generated when the head impacts whatever object lies in its path. If the patient falls upon soft earth, the possibilities of injury are not too great. On the other hand, if the patient should fall and strike a sharp, firm object with his head, the possibilities for severe injury are quite large. When one considers that these patients are completely mobile and engage in normal activities including vigorous physical exercise with the possibility of seizures as high as 20 per day, it is readily apparent that severe injury can result. Efforts have been made to provide protection to the heads of these patients at the Western Carolina Center. Through the efforts of the Western Carolina Center and the parents of the patients, the best obtainable crash helmets have been purchased and used. The helmets that seem most useful are the NASCAR racing helmets used in stock car racing. These helmets do provide protection to the patient's head within the area underneath the helmet. Even so, a severe fall frequently results in severe bruising of the patient's head when the cushioning material is completely compressed and the helmet transmits a significant portion of the shock to the patient's skull.

Because of the inadequate cushioning of the foam rubber material used in these helmets, severe bruises and lacerations have occurred in areas that should have been protected by the helmet itself. These bruises have resulted in swelling of the patient's head to the extent that the helmets could not be worn. This, of course, compounds the problem since this deprives the patient of all protection.

After examination of the helmet design and the cushioning material contained in the commercially available helmets, the Team suggested the use of the NASA-developed Temperfoam (Dynamic Systems, Route 2, Leicester, N. C.) as a potential solution to this particular problem. Information was given to the researcher on sources where the Temperfoam could be purchased. It was suggested that a laminated Temperfoam liner be employed

using a softer inner material in contact with the patient's head and a firmer grade of Temperfoam between the soft material and the fiberglass helmet structure which would absorb the impact force generated by falls. In this way it was hypothesized that maximum comfort could be obtained within the constraints of providing the necessary firmness to prevent complete compression of the Temperfoam cushioning material during impact.

Two helmets (see Figure 6) were fitted with the Temperfoam material and used by the patients (see Figure 7). Head injuries of the patients in the area protected by the helmets were drastically reduced by the use of Temperfoam. A test of 4-months duration was conducted, and comparisons were made with previous effects of the falls on the patients. The nurses were not told of the new lining material in the helmets so that unbiased reaction might be obtained. After several months use, the nurses began to note and make known to the problem originator the fact that injuries sustained in falls were significantly less severe than those that had previously been experienced. These tests clearly demonstrated the superiority of the Temperfoam material as a cushioning agent over that used in the commercially available helmets. The problem originator was very enthusiastic in his praise of the results obtained using the NASA-developed Temperfoam material. He anticipates that, in all future cases at the Western Carolina Center involving such protective head gear, Temperfoam will be used.

Fortunately, modern medicine has controlled many epileptic problems so that the need for protective helmets is not widespread. Although the use of Temperfoam in protective helmets is not widely required, the use of NASA technology has directly improved the injury problem of these young men.

PROBLEM TU-29 *Damage to Blood from Microwave Heaters*

A technique developed for analysis of the blood of astronauts exposed to high oxygen pressures has been used to analyze the effect of microwave blood warmers.

Warming of refrigerated (4° to 6°C.) bank blood has become a common clinical practice because of the difficulties encountered with transfusing cold blood. Clinical studies have left little doubt that rapid transfusion of large quantities of blood at refrigerator temperatures may be a dangerous practice resulting in cardiac or general body hypothermia. Warming of the blood before infusion reduces the morbidity and mortality of the recipients. To avoid the effects of cardiac and general hypothermia during massive hemorrhage, cold blood should be warmed to body temperature when rapidly administered in large amounts.

Until very recently, the basic method of warming refrigerated blood involved the use of some form of water bath heat exchanger. Because human blood at 4°C. is a highly viscous fluid, coil heating systems cannot attain sufficient flow since they must force cold blood through a filter before warming. The method is relatively inexpensive, but the apparatus requires considerable warm-up time as well as some blood for priming. In addition, the precise temperature control is difficult to achieve,

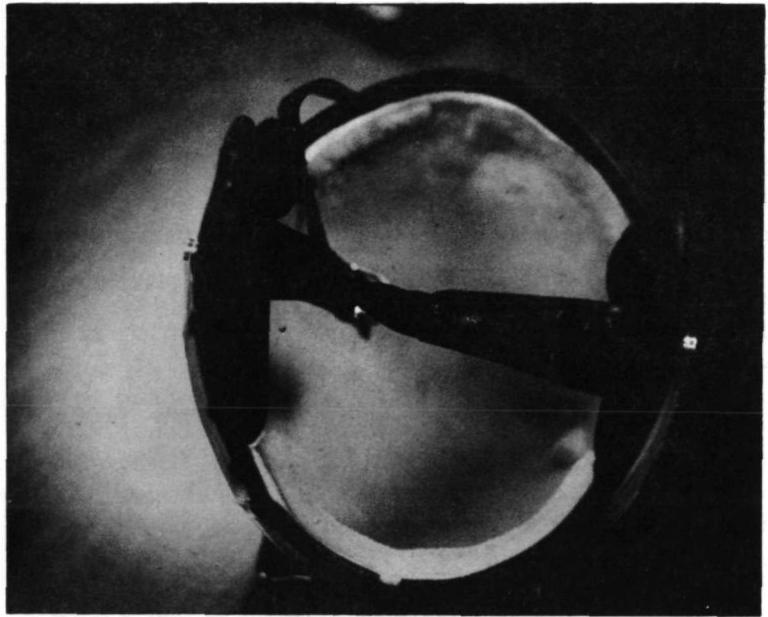


Figure 6. Helmet with Temperfoam Lining



Figure 7. Patients Wearing Helmets

and the unit must be placed close to the patient, thus adding to the equipment clutter in an already crowded operating room. Recently, the use of microwave blood warming has eliminated these problems by warming the blood in the bag before filtering, which offers speed, economy, and ease of use. The refrigerated blood can be heated to a desired temperature in 1 minute. Blood is heated only when needed so there is no wasted blood.

Microwave heating is unique in that it does not involve a hot object with the transfer of heat through conduction, radiation, or convection. Instead, electromagnetic energy is generated at a very high frequency (2.5 gigahertz) by a special oscillator tube. This sets up an alternating electromagnetic field which causes the molecules within the blood to continually try to realign themselves electrically with each field reversal. The friction between these moving molecules generates heat, thus converting electromagnetic energy into thermal energy.

Although initial tests on the use of microwave heated blood indicate that the method is basically safe, the rapidly increasing use of microwave warming demands that a more subtle test of blood damage be used to determine whether the method is safe in all circumstances. The basic problem is to find a method of determining subtle damage to blood from the microwave heating.

The potential solution to this problem was discovered as a result of a problem statement circulation in regard to problem TU-25, "Measurement of Blood Damage from Heart Lung Pumps." In response to that problem statement, Dr. Stanley Ellis of Ames Research Center suggested the use of an enzymatic technique. The technique is used at Ames for measuring the effect of high oxygen pressures in blood cells. In particular, the technique uses a proteolytic enzyme that can be monitored in a simple manner and with very high sensitivity using a specific substrate. The enzyme is dipeptidyl aminopeptidase III, which was first purified and characterized from the pituitary gland and which can be specifically determined by means of the fluorogenic substrate, arg-arg-beta-naphthylamide. [J. Biol. Chem. 242, 4623 (1967)]

The problem originator discussed the basic technique with Dr. Ellis who then agreed to process some initial samples of microwave warmed blood. The problem originator sent 12 units of blood to Ames Research Center for analysis using the Ames enzymatic technique. The initial tests revealed that some of the microwave warmed blood did, in fact, have a high reading using the enzymatic technique. However, not all microwave warmed blood gave the same response, which indicated that other factors were obscuring the basic phenomenon. Therefore, the problem originator sent additional samples to Ames for evaluation. These results showed a correlation with microwave damage to the blood. The problem originator reported the results at the 1973 Conference of the International Anesthesiology Research Society to be held at Bal Harbour, Florida.

This technique has provided new research knowledge about microwave blood warming techniques, which are commonly used in major medical centers throughout the country.

PROBLEM WF-114 *Improved Utilization of Laboratory Computers*

Techniques developed at Marshall Space Flight Center have been utilized to expand the capability of a small computer in a university medical center.

Experimental research is underway to analyze the response of animals to various drugs that affect the cardiovascular system. The experimental procedure is as follows: The animals are surgically prepared to measure a number of parameters, e.g. coronary blood flow, blood pressure, heart rate, etc., and a specified amount of a particular drug is injected into a vein of the animal. A number of different drugs are employed that are intended to either improve the performance of the heart or to attenuate the performance of the heart in the presence of atherosclerotic disease. The animals have been placed on special, atherogenic diets for up to 3 1/2 years to induce atherosclerosis. About \$1,500 to \$2,000 is invested in each animal in animal care alone.

As a result, the value of each experiment and the observations are extremely important because, after the experiment is completed, the animals must be sacrificed, and the experiments cannot be rerun. It is important to know during the actual experiment how the data being obtained compares with what has been seen in previous experiments. Since as many as 10 parameters are being monitored with 20 or 30 drug responses involving 6 or 7 drugs during a single experiment, it is just not possible to look at a current response and make the decision as to whether a given, particular trial is yielding "good" data or whether it represents an abnormal response.

In order to make a decision concerning the validity of the current data, it is desired to have available to the researcher during the experiment in real time, the updated mean and standard error of the mean for each drug and each monitored parameter from all previous experiments. Obviously, standard computing techniques can easily accomplish this using a computer. The problem lies in the real-time requirement and the fact that most research laboratories have only small computers.

Many labs do have computer terminals and access them by way of, generally, a low speed data transfer device like a teletype. Data can be transmitted to and received from a central computer in this manner. This does not, however, provide the computer data back quick enough. Most laboratories do not normally have access to high speed analog devices to permit real-time operation. In this problem the basic requirement is to update the current statistical picture of the terminal program to date; that is, the average and the standard error of the data trials, including the current data, are needed in real time. The processing by which average laboratory statistics are determined is one in which each element of data is taken, a card is punched, and the deck of cards is taken to the computer center. Then one must wait for the computer to perform the statistical analysis in order to get the processed information back. This procedure is obviously too slow for the problem at hand.

Using the LINC computer, available in the researcher's laboratory, and standard statistical analysis routines, there is just too much data. It is not possible to process the data because of the small data storage capacity of such machines. Fundamentally, the limited storage capacity (memory) of the LINC prohibits real-time statistical analysis. The LINC has only 1,000 words of data storage and 1,000 words of program storage.

If the research laboratory had a direct high speed analog line to the Computer Center at Bowman Gray School of Medicine, it would be possible to perform the computations in real time; however, from a practical standpoint, it is not practical to allow a single research laboratory to have sole and direct access to the central processing facility for 7 hours (individual experiments average this length of time). Even with the LINC, it is relatively easy to compute the average. The standard error is more complicated to obtain in terms of computation complexity. To determine the standard error, the algorithm requires access to each individual element of data. Fundamentally, the average and the standard errors of all previous trials are needed in real time during the experiment so that comparison of the current response to these data can be made. If this average and standard error data is made available during the experiment in essentially real time, it permits the researcher to determine whether the current response is acceptable.

This problem was solved as a result of discussions with and suggestions from Dr. Fritz Krause of Marshall Space Flight Center. Dr. Krause has developed statistical updating routines and piecewise statistical analysis procedures that are pertinent to this problem. Basically, the techniques developed by Dr. Krause permit one to take a long duration data record and break it up into segments, sample the data, and treat this process statistically in a meaningful way. By sampling the data (rather than using the entire data record) the computer storage capacity is drastically reduced so that the computation can now be accomplished with a small laboratory computer such as the LINC. Dr. Krause has also proved the statistical validity of these techniques, which, of course, had to be done before the techniques could be used.

Use of these techniques permits the researcher to look at the mean of all the responses of all the previous experiments with other animals up to that time and compare the current response with the mean of the previous responses. This essentially gives the research a running statistical picture of all the previous data of drug responses. In the experiments six different drugs are used, so it is necessary to look at each drug and each parameter for the mean and the standard error of the mean. By comparing the current response with the mean and the standard error of the mean for all the drug responses of the particular drug up to the current response, it is possible to decide whether the data being currently obtained is good data or abnormal data. The standard error of the mean is very useful in making this decision meaningfully.

If the data is considered good data, then the current response is included, the data is updated, and a new mean and standard error of the mean are obtained very rapidly and with very little programming effort.

If the response is abnormal (different), then there are a number of things associated with the experimental technique that could cause abnormal response data; there may be bubbles in the transducer systems, the animal may not be anesthetized properly, the drug may not have been administered properly, etc. Since the implementation of this transfer, it is now possible to detect when a response is abnormal and then check the entire experimental setup and make the necessary corrections. Then the drug is given again to obtain good data.

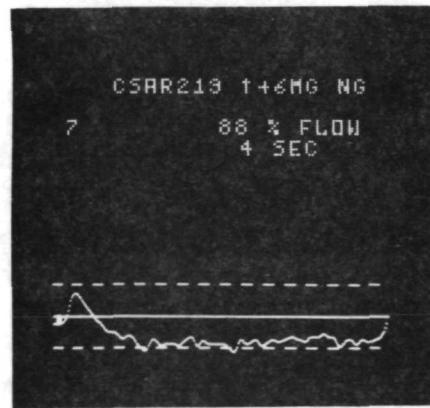
Consequently, by having the mean and standard error of the mean available, the researcher is able to detect abnormal data, while the animal is still alive, and make the necessary corrections to obtain good data. It makes the difference between obtaining reliable data and discovering, after the animal has been sacrificed, that the experiment did not yield any useful information. It gives the researcher the opportunity to take a second look at something that may be questionable, and improves consistency and reliability in the experimental technique as well.

If the data for a single experiment were updated by hand, it would take someone 2 weeks to do it. Using the techniques developed by Dr. Krause, the existing LINC computer can accomplish the same thing in about 20 seconds. The period of time is very important because with only a 20-second wait the researcher is now able to make the comparison with other data while the animal is still alive. But more importantly, if the data is abnormal the experiment can be run again while the animal is still alive to determine where the cause of the abnormal data lies, and thus provide the opportunity to obtain good data which would otherwise be relegated to the scrap heap as a bad experiment. This is of some significance when one considers the time involved in preparing and conducting the experiment plus the animal cost of several thousand dollars. An example of experimental use of this technique is shown in Figure 8.

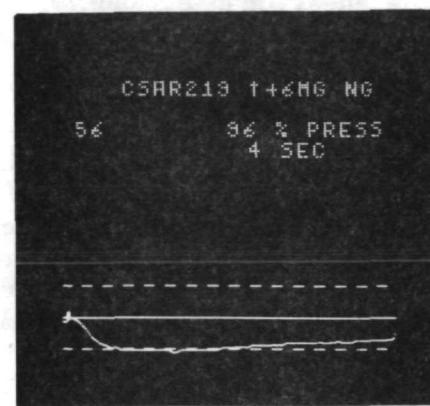
This technique has applicability in any laboratory where data analysis is limited by computer memory. Although the technique was installed on a computer that is not widely used, it can be easily implemented by a computer programmer who has knowledge of the algorithm. This will become widely available when the problem originator publishes a paper, now in preparation, that describes the technique. The use of this technique will significantly enhance the capability of medical researchers to analyze slowly varying biological signals that have a poor signal-to-noise ratio.

PROBLEM VAM-2 *Diagnosing Gait Abnormalities*

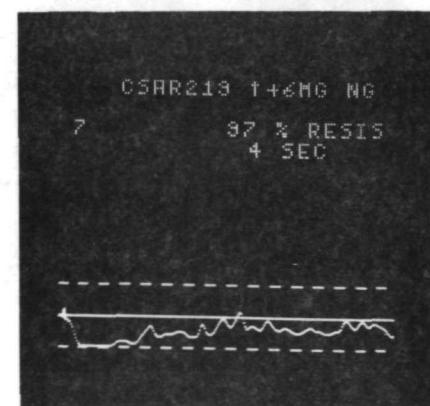
Thousands of Americans suffer loss or impairment of their limb functions. Artificial limbs and therapeutic treatment offer a degree of rehabilitation to many of these persons who are then able to resume many of their normal activities. Presently, gait abnormalities are diagnosed and



(A) Flow



(B) Pressure



(C) Resistance

Figure 8. Example of Cardiovascular Data Calculated Using Piecewise Statistical Analysis

progress is followed by a physician's visual observation of the patient while walking. The physician has little trouble in determining the type of affliction (e.g., Parkinson's disease, cerebral palsy) by his observation of the patient. However, it is difficult to determine the degree of impairment of gait function. The use of subjective, qualitative information, however well based in elucidated rationale, leaves much to be desired and is usually questioned by those not originating the information. Lack of an objective record is a definite handicap to communications among clinics and even in the same clinic when extended follow-up of a patient is desired. Two primary objectives must be achieved in order to fulfill the needs of orthopedic and rehabilitation clinicians:

- (1) The selection of an approach to gait analysis that permits the definition and display of significant parameters of gait in a manner meaningful to clinicians; and
- (2) The implementation of appropriate hardware necessary for this approach. Further, the hardware must be relatively simple, low in cost, and should require only minor modification of existing clinical facilities.

The earliest studies of human and animal locomotion were based upon keen observation and anatomical dissections. Multiexposure photography was one of the first technologies to be utilized for the gathering of objective data in the late 19th century. Since then, and especially in the past 25 years, efforts have been made to employ a variety of technologies, as they became available, to the problem of studying human locomotion. Devices such as accelerometers, electrogoniometers, electromyography, high speed photography, and strain gage instrumented force plates have been employed separately or in combination to measure various parameters of human locomotion.

The problem originator was initially concerned with the application of miniature accelerometers to determine the acceleration of limb segments during walking. The problem was posed to Mr. John Samos, Technology Utilization Officer at NASA's Langley Research Center (LRC), who contacted an LRC engineer experienced in accelerometer instrumentation. Discussions with this engineer revealed that there were several problems involved in instrumenting a patient with accelerometers and that an alternate approach should be considered. Mr. Samos then contacted Mr. Bill Howell and Mr. Gordon Bullock of the Langley Guidance System Research Section in order to consider new approaches to the problem of human gait analysis. After careful consideration of the problem, Mr. Bullock and Mr. Howell suggested the use of miniature magnetometers which could be attached to the patient's leg (see Figure 9) to determine the orientation of limb segments during ambulation. A magnetometer is a device for measuring the intensity of a magnetic vector. The earth's magnetic field can be employed as a convenient reference vector since, for a given location, it is easily determined and is relatively constant.

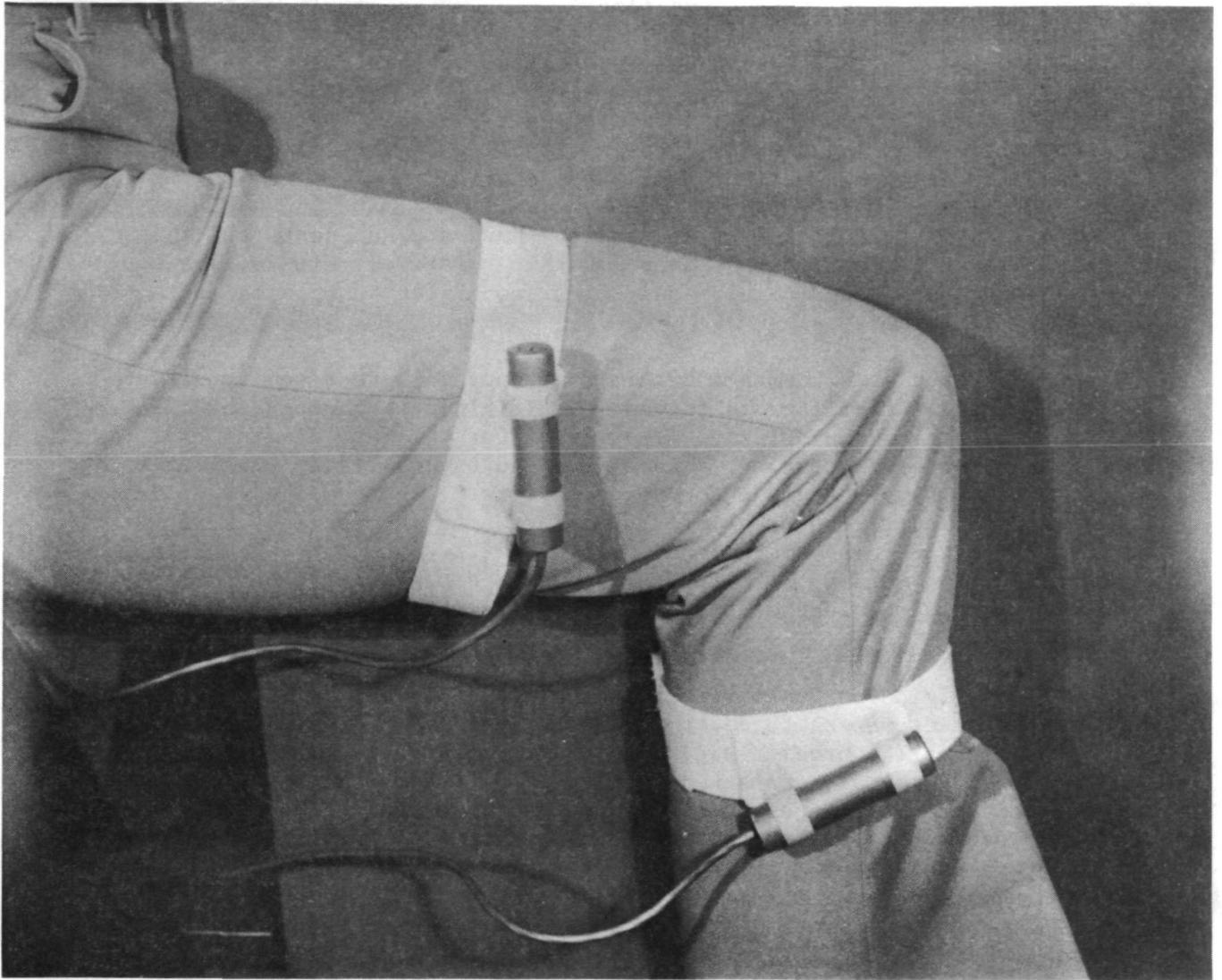


Figure 9. Magnetometers Used for Gait Analysis.

The problem originator visited LRC where he received a demonstration of the magnetometer angle sensing technique applied to the problem of gait analysis. Langley Research Center supplied the problem originator with two magnetometers so that a feasibility study could be conducted in a clinical environment. The magnetometer instrumentation technique was utilized at the University of Miami and was found to give reliable results while being relatively simple and inexpensive to apply. The angular orientation of the body's limb segments has been previously obtained quite reliably by high speed photography. Photographic methods, however, have the disadvantage of requiring a large amount of time (approximately 18 hours) to obtain and display data for a single subject. The magnetometers make possible the collection and display of patient data in real time, thus making the magnetometer instrumentation technique attractive for clinical use. Typical results for normal patients are shown in Figure 10 and 11.

Two publications have resulted from this technology application: an invited paper that was presented at the 5th Annual Southeastern Symposium on System Theory in March 1973 and a second paper scheduled for the 26th Annual Conference on Engineering in Medicine and Biology which will be held in October 1973. In addition, the Team has received a request for information on the magnetometer sensing technique from three other groups studying human locomotion. The Team feels that the presentation of the results of the magnetometer experiment at the 26th Annual Conference on Engineering in Medicine and Biology will generate widespread interest in the technique among kinesiologists across the country.

PROBLEM VAM-13 *Corrosion and Fracture of Orthopedic Implants*

A NASA metallurgical research team has determined the cause for failure of orthopedic implants.

Metals and alloys are currently used in a number of bioassists such as pacemakers and heart valves. The most widespread use of metallic implants is found in a multitude of orthopedic devices. One of the most common examples of an orthopedic implant is the fracture brace which consists of a stainless steel plate and stainless steel screws for attaching the plate to the bone. The plate serves to hold the bone in place while the fracture mends as well as to give added support to the fractured region. In healthy persons, the implant will usually be removed after the fracture has healed. In many instances, however, the plate will fracture prior to the healing of the bone. When an implant fails in service, it must be removed immediately. In the aged or in persons having a poor state of health, the trauma of a second operation to replace the fractured implant may severely hamper the patient's ability to recover.

A recent study indicates that the incidence of fracture is on the order of 9 percent. There have been few comprehensive investigations of the causes of failure of metallic orthopedic implants where both patient history and metallurgical examinations can be combined to conduct a

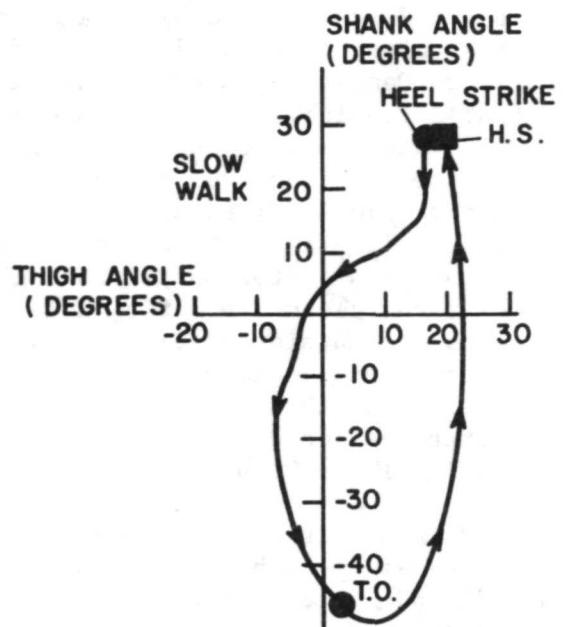


Figure 10. Thigh-Shank Angle Chart for Slow Walking.

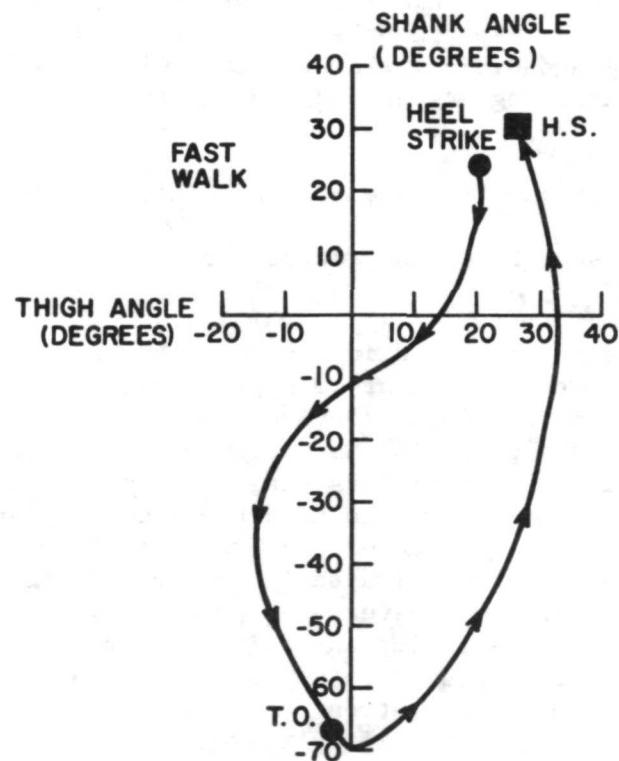


Figure 11. Thigh-Shank Angle Chart for Fast Walking.

complete analysis of the initialization of the failure mechanism. The problem originator had obtained fractured implants from several clinical institutions in Florida and wished to obtain competent assistance in determining the causes of failure. A better understanding of the causes of failure should lead to improved metallurgical and manufacturing procedure and perhaps to improved surgical procedures for implanting orthopedic devices.

Mr. John Samos, Technology Utilization Officer at LRC, referred the Team to two engineers, Dr. Bland Stein and Mr. Barry Lisagor, who were interested in studying the problem. The problem originator visited Langley to discuss the problem in detail and brought with him samples of failed orthopedic implants. Two of the implants had failed soon after implantation: one had failed within 1 week and the other within 5 weeks. These samples offered a unique opportunity to study the nature and mechanism of early failure. Although such early failures are not uncommon, a study of implants that failed soon after implantation has not been located in the literature.

Mr. Barry Lisagor conducted an analysis of several failed orthopedic implants using the Langley scanning electron microscope (see Figure 12) and the electron microprobe. The underlying cause of fracture in the implants studies is thought to be stress corrosion. Mr. Lisagor, a member of the ASTM Subcommittee on Stress Corrosion, presented his results of the analysis of failed orthopedic implants to the Stress Corrosion Subcommittee in December 1972. The subcommittee concurred that stress corrosion rather than fatigue was the probable cause of failure in the implants studied. The Stress Corrosion Subcommittee became interested in this problem and formed a task group with Mr. Lisagor as its chairman to study in detail how orthopedic implants fail. As task group chairman, Mr. Lisagor has frequent contacts with the ASTM Subcommittee on Orthopedic Implants. Mr. Lisagor is also coordinating his efforts with the National Bureau of Standards. At this point it is not entirely clear whether the stress corrosion is caused by residual stresses in the material, due to the manufacturing process, or by the surgical procedure of attaching the implant to the bone (e.g., bending the implant to fit properly). The body's environment serves as a catalyst to hasten the fracturing process.

Although other groups in the country have recently conducted failure analyses of orthopedic implants using a scanning electron microscope, the Langley study does much more than corroborate previous results. One important point in the Langley study was the opportunity to study the mechanism of orthopedic implants. Because of his recognized competence among members of the Stress Corrosion Subcommittee and his rapport with the Surgical Implant Subcommittee, there is, apparently for the first time, an effective line of communication which may bring about more stringent requirements in the fabrication and use of orthopedic implants.



Figure 12. Electron Micrograph of Hip Pin.

PROBLEM WWRC-11 A Valve for Leg Bag Urinals

Using the results of a solution to a different medical problem, the Team has simplified the control of leg bag urinals.

Many handicapped people do not have control of their urinary functions. These people must wear a polyethylene bag strapped to their leg which collects the urine. The present leg bag urinals have a tube coming out the bottom end of the bag which is used to empty the urinal. The tube is closed by a clamp which compresses the tube thus preventing the flow of urine except when the patient wishes to empty the bag. The presently used clamp must exert a significant amount of pressure on the tube in order to eliminate all leakage. Unfortunately, the clamp is very difficult to operate in that it requires a large amount of force and significant manual dexterity to either open or close. The people who wear these leg bags generally have severe disabilities and experience great difficulty in operating these clamps. Another means of draining the leg bag urinal is desired. Whatever valving system is employed must permit easy operation. Exertion of pressure is the most effective mode in which these patients can perform a controlled action. Therefore, the best method for operation as far as the handicapped patient is concerned would be in a compression mode; that is, it is desired that the valve technique be capable of operation by the application of pressure not to exceed two pounds, preferably less.

When this problem was received, the Team realized that the specially developed check valve used in the fabrication of Applications Engineering Project WF-3, "Prosthetic Urethral Valve," might potentially be useful in this particular application since this check valve could be actuated by a simple pressure application. The details of this check valve were discussed with the medical investigator. As a result of the evaluation of this suggestion, it was concluded that the check valve from the prosthetic urethral valve had potential as a solution to this problem. In order to perform an actual "in use" evaluation of the valve, one was obtained from the investigator who performed the application of engineering on the prosthetic urethral valve. The main question was whether or not the patients could actually actuate the valve whenever desired. The "in use" evaluation by the medical investigator determined that the patients could operate the valve very effectively.

It was also apparent that the small diameter of the valve would require an inordinantly long time to empty the leg bag urinal. The medical investigator advised the Team that if two prototype valves could be obtained and modified to the proper size, then full evaluation could be completed. In addition, the medical investigator contacted commercial suppliers to discuss the possibility of having a commercial supplier manufacture these devices for widespread use.

Two prototypes were constructed and evaluated by the medical investigator. It was determined that there was a significant improvement over previous leg bag valves and allowed the handicapped individual to effectively use the valve. (See Figure 13)

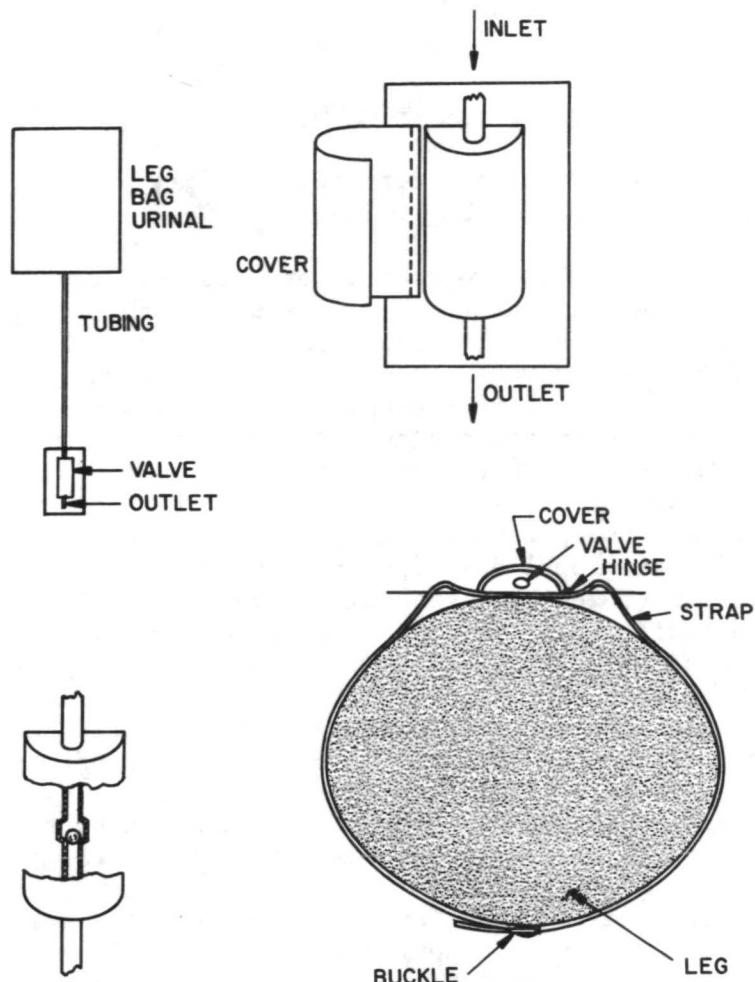


Figure 13. Urinal Leg Bag Valve (Prototype).

This innovation has recently attracted the interest of an industrial group who may manufacture this technology application. This possibility will be actively pursued in order to maximize the availability of this innovation to the medical rehabilitation community.

2.2 Potential Technology Applications

During the reporting period, four problems achieved the status of potential technology applications. This status indicates that an adequate solution to the problem has been identified and implementation is in various stages of accomplishment. These four problems are discussed in the following summaries.

PROBLEM NCI-13 Portable Isolation Garment

A garment designed to isolate Apollo astronauts upon return to earth has been used to provide a portable sterile environment for cancer patients undergoing chemotherapy.

The National Cancer Institute (NCI) has pioneered the use of laminar flow rooms to provide sterile environments for patients undergoing chemotherapy. This is required because the various drugs used in the treatment of diseases such as leukemia cause a severe reduction in the number of white cells, and thus, the patient has a high risk of contracting an infectious disease. The second benefit, which is as yet unexplained, results from the fact that the patient is able to tolerate higher drug doses in the sterile environment than in the normal environment. For the past several years the National Cancer Institute has treated adults in these laminar flow rooms with great success and, recently, they have started using the rooms in the treatment of children. In comparison with adults, children are less able to psychologically tolerate confinement to one room, so it is desirable to be able to remove the patients from the laminar flow rooms for brief periods while still maintaining a sterile environment. In addition, it is important to permit the patient to be transported to another part of the hospital for a medical procedure such as diagnostic X-ray or therapeutic radiation. Unfortunately, no such portable isolation chamber existed for these patients. The basic problem is to provide a sterile environment by filtering the air (remove particles greater than $0.3 \mu\text{m}$) in order to reduce the possibility of infection from a variety of airborne particles.

Mr. William Z. Penland of the National Cancer Institute contacted Dr. F. T. Wooten of the RTI Biomedical Application Team in October 1972 to ask for assistance in solving the problem of providing a portable isolation chamber for patients outside of the laminar flow room. It would be desirable to be able to remove these patients for periods up to 4 hours. Dr. Wooten identified the NASA Biological Isolation Garment (BIG) (see Figure 14) as a possible solution to this problem and contacted Mr. John T. Wheeler, Technology Utilization Officer at the Manned Spacecraft Center (MSC), who quickly identified Mr. Fred Spross as the cognizant technical staff member at MSC. Following technical discussion of the problem with Mr. Spross, Mr. J. C. Stonesifer of MSC forwarded a NASA BIG to NCI for their evaluation. The NCI staff used the BIG with normal individuals in order to determine its relevance to the particular problem. The quick loan of this garment to NCI stimulated their interest in this particular problem and expanded the basic idea to provide for its use in a wider range of applications.

The NASA Biological Isolation Garment is described in NASA Patent No. 3,516,404, which is listed in the NASA document file as N71-17599. The NASA BIG was designed for the Apollo astronauts to wear upon return to earth in the splashdown phase. The unit was designed to be specifically worn from the time of egress from the command module to the time of arrival in the portable quarantine facility on board the recovery carrier. The



Figure 14. Apollo 11 Astronauts Wearing Biological Isolation Garment.



Figure 15. Prototype Modified Biological Isolation Garment.

NASA garment was designed to prevent contamination of the earth environment in the event that the astronauts were carrying some micro-organism. Thus, the NASA unit was designed for the inverse problem of the National Cancer Institute problem. The NASA unit was designed to prevent contamination of the earth's environment by the astronaut whereas the NCI application is designed to prevent contamination of the patient by the earth's environment.

The major problem with the existing BIG concerns discomfort caused by heat and the claustrophobic aspect of the face mask. The NASA garment was designed for use with healthy adult males who are better able to tolerate a face mask than a seriously ill patient. The existing face mask also accounts for part of the total weight of the garment and it would be desirable to reduce the weight if possible. Thus the NCI personnel decided to add a positive pressure portable air supply, which will offer advantages not only in the area of heat and weight reduction but also from the standpoint of contamination control. For example, many of the contaminants come from the surface of the patient's body; providing a directed flow of air from the top of the head downward would reduce the danger of self-contamination. The reduction in sealing requirements might also reduce the need for pressure sealing zippers, which are more difficult to operate than a simple Velcro fastener.

The NCI research team asked one of its contractors, Arthur D. Little, INC., to design a garment based on the NASA design but modifying the face mask to better suit the needs of the NCI patients. The contractor has performed extensive analysis of the flow in the existing BIG and has been able to incorporate the relevant features of the NASA garment into the NCI garment. A prototype (Figure 15) of the NCI garment has been built and delivered to NCI for clinical evaluation.

When this technology application is complete, it will be an excellent example of how technology utilization should work. It is apparent that in less than 1 month, it was possible to deliver to the NCI research team a garment that incorporated many of the desirable features needed for this problem. Utilizing the experience gained in the development of the NASA garment, the NCI research team was able to go immediately to a prototype design which will save significant time in bringing a needed technological development into clinical practice.

This garment is expected to have use wherever the laminar flow concept rooms are used in chemotherapy. These rooms are used extensively now by the National Cancer Institute, and several hospitals are building facilities for their use.

PROBLEM TU-33 *Silica Measurement in Microgram Quantities*

A technique used by a NASA research team for analysis of small dust samples has potential for analyzing small quantities of silica dust collected in research on silicosis.

Silicosis is a disease of the lungs caused by inhalation of dust containing free crystalline silica over a prolonged period varying from 5 to 25 years.

Industrial processes that result in dispersion of free silica into the air include the mining of lead, hard coal, copper, silver, and gold; sandstone and granite cutting; metallurgical processes using free silica; and the manufacture of silica abrasives. Only dust containing small particles of free crystalline silica (less than 10 micrometers in diameter) can cause silicosis. The allowable maximum concentrations in industrial dust are stated to be around 25 million particles per cubic foot of air if the free silica content of the dust is less than 10 percent but down to 2.5 million particles per cubic foot if the silica content is greater than 50 percent.

When free silica particles are taken into the small pulmonary passages, a local fibroblastic proliferation occurs with a resulting decrease in maximum breathing capacity. As silicosis progresses, pulmonary function is gradually decreased as silicosis reduces the vital capacity of the lungs.

Although silicosis has been studied for many years, a new form of the disease has recently appeared. This disease, called accelerated silicosis, can result in death after 3 years of exposure as compared with the more typical 25-year period for miners. Accelerated silicosis has been found to occur frequently among workers engaged in sandblasting, e.g., as commonly used on the drilling platforms in the Gulf of Mexico. Staff members at the Tulane School of Medicine have noted a rise in the occurrence of accelerated silicosis with the increase in number of drilling platforms off the coast of Louisiana. A study is now underway to characterize the environment of the workers who are susceptible to this disease. A method exists for the sampling of the air around the workers that produces only microgram quantities of the dust. A method for analysis of the silica content of these small samples is necessary, in order to carefully characterize the environment of the workers.

Between 30 and 300 micrograms of the dust is contained on a 50-milligram filter. The filter is a 0.8-micrometer Millipore type, and an analysis procedure with a precision of \pm 5 percent is desired.

The problem originator investigated wet chemistry and X-ray diffraction methods but found these to be unsuited for the very small sample sizes obtained from the workers.

Mr. John Samos, Technology Utilization Officer at the Langley Research Center (LRC), noted this problem in one of the Team's monthly reports. As a result, Mr. Samos identified Dr. Roger Jolly of LRC as an individual knowledgeable in this area. Dr. Jolly suggested the use of X-ray fluorescence techniques that have been used at the Langley Research Center.

Following a conversation between Dr. Jolly and the problem originator, it became apparent that the proposed method had a high probability of solving this problem. Dr. Jolly has volunteered to analyze some experimental samples and, in addition, the problem originator plans to visit Dr. Jolly to learn more of the details of the technique.

If successful, this research tool will provide additional insight into the cause of a crippling or fatal disease.

PROBLEM UNC-73 *Image Intensifier for Microscopes*

The human disease producing micro-organism, *Mycoplasma Pneumoniae*, is responsible for about half of all pneumonia occurring during adolescence and young adulthood. Basic research to identify a vaccine to combat this micro-organism is being conducted. This research uses the widely used technique of microscopy immuno-fluorescence.

Microscopy immuno-fluorescence takes advantage of the phenomena of fluorescence to locate and quantitize a micro-organism present in a tissue specimen or culture. A fluorescence dye is attached to an antibody. The tagged antibody attaches itself to a specific antigen which is the disease producing micro-organism. A tissue specimen containing the antigen is then illuminated with ultraviolet light while being examined under a microscope. The fluorescent dye gives off tiny amounts of light thus revealing the location and quantity of the micro-organism present.

Since the specimen is constantly changing, a record is made by photographing the specimen through a microscope. Polaroid black and white film having a film speed of ASA 3000 is used. Unfortunately, the results are not altogether satisfactory. The amount the specimen can be illuminated is limited because excessive light burns out the fluorescent dyes. The limited lighting requires long exposure times, but the length of exposure is limited because the fluorescent dye has a relatively short half-life. As a result very little detail other than the fluorescence can be caught on film.

The potential solution to this problem was discovered as a result of a response to a preliminary problem statement. Mr. Wayne Chen of Goddard Space Flight Center (GSFC) suggested the use of a special image intensifier used in NASA's photographic work in astronomy.

The image intensifier is mounted on a 35 mm Nikon camera and provides a thirtyfold increase in film speed. It has been used extensively and very successfully by Mr. Larry Dunkelman at GSFC.

The problem originator discussed the technique with Mr. Dunkelman and Mr. Chen. Mr. Dunkelman agreed to bring the image intensifier to the University of North Carolina Medical School for evaluation upon receipt of a Nikon 35 mm camera system designed for the microscope. It is anticipated that this aerospace development will significantly improve the research capability of the medical research team.

PROBLEM WF-116 *Organ Preservation*

Experience gained by NASA in handling liquid rocket fuels has been applied to preservation of human organs during surgery.

There are a variety of diseases, infections, and obstructive conditions that can lead to renal failure. It has been estimated that 55,000 persons in the United States die from irreversible kidney failure each year.

This figure may climb to 100,000 if one includes death attributable to conditions such as hypertension or stroke which may be secondary to an underlying kidney ailment. The problem originator has been engaged in a long-term study of kidney stones: their occurrence, causes, and surgical techniques for restoring kidney function. A significant portion of the population is affected by kidney stones. Passing kidney stones is an extremely painful process and stones that are not passed can frequently cause severe problems that eventually necessitate surgical intervention to remove or repair the kidney. The ailing kidney can be removed and its function assumed by the other so long as the patient has one perfectly functional kidney. If the second kidney is not completely functional, a kidney transplant or artificial dialysis may be required. Because of the numerous problems associated with both organ transplantation and the sustenance of life by artificial dialysis, the problem originator has developed surgical techniques for restoring function to ailing kidneys that would customarily be removed. The operation to remove a kidney stone may take up to 4 hours. During this time, the renal artery which supplies blood to the kidney is clamped off. Thus, it becomes necessary to maintain the viability of the kidney during the operation. The problem originator preserves the intact kidney by placing it in a rubber sheet and then packing it in a ice slurry. Ice slurries are currently made by supercooling a solution of sodium chloride in water. The supercooled liquid becomes a slurry upon agitation; a skilled physician assistant can therefore make the necessary slurry by slowly pouring the supercooled sodium chloride solution into a chamber. Prior to the operation, several bottles of the sodium chloride solution are placed in a freezer to become supercooled. The bottles are agitated by hand every 10 minutes to prevent the solution from solidifying. During the operation, bottles of the supercooled sodium chloride solution are removed from the freezer as needed for making the ice slurry. Frequently, the solution solidifies inside the bottle, due to inadvertent agitation, and becomes unusable. A method of making an ice slurry upon demand would assure that enough ice would be readily available for the operation and would eliminate the need for frequent agitation of the bottles to prevent solidification.

The Team and Mr. Juan Pizarro of Marshall Space Flight Center (MSFC) were able to identify two NASA engineers, Mr. Eric H. Hyde and Mr. Armis L. Worlund, who were involved in a program aimed at the utilization of hydrogen slush as a rocket propellant. Long duration space missions require propellants that can be efficiently stored and have a high specific impulse. Slush and subcooled cryogens fulfill both requirements. During the past 5 years MSFC has sponsored a number of studies relative to manufacturing, handling, and instrumenting slush systems. Team members met with Mr. Worlund and Mr. Hyde to discuss the problem of providing a slush for a kidney preservation in the operating room. After considering the problem in detail, the NASA engineers suggested a simple technique for making an ice slurry upon demand which appears to be quite adequate. Rather than to supercool the sodium chloride solution as is now done, they suggested cooling the sodium chloride solution to approximately 1° above freezing. At this temperature there would be no problems with the

liquid solidifying when being emptied from the bottle. The solution could be easily poured into a vacuum chamber and the subsequent application of a slight vacuum would cause the solution to freeze. The vacuum pressure could be controlled to produce only the desired amount of slush. The slush could be applied as needed to the kidney. Plans to implement the proposed solution are currently underway by the problem originator.

2.3 Impacts

The Application Team's efforts often provide a significant benefit to the researcher even though no technology application has been accomplished. During this reporting period, Team activities had a significant impact on the researcher's activities in two such problems that are discussed in the following summaries.

PROBLEM MISC-29 *Nurse-Call for Quadriplegic*

There are many persons for whom conventional pushbutton nurse-call switches are useless. Among those who cannot use conventional nurse-call switches are patients who cannot exercise voluntary control over arm or hand muscles (e.g., quadriplegics, multiple sclerosis patients, etc.) as well as patients incapacitated by burns on upper extremities. Many of these patients depend upon the services of nurses for practically all of their needs. Improved nursing care could be provided by the installation of a nurse-call switch that could be actuated by the patient. The patients requiring such a signalling system generally have voluntary control over one or all of the following functions that could conceivably be used to actuate the switch:

- (1) Breath;
- (2) Eye movement and blink; and
- (3) Head motion.

Generally, complicated systems that require frequent adjustments or maintenance are undesirable because of the lack of skilled technicians in most hospitals.

This particular problem originated at the Conway Nursing Center in Conway, S. C., where there is a quadriplegic who has no voluntary control over his limb muscles.

The breath-actuated switch conceived at NASA's Langley Research Center and originally implemented by the Southwest Research Institute BATEam provides a novel solution to this problem. The heart of this system, commonly called the puff-switch, is a microswitch that can be actuated by as little as one-half ounce of force. The force produced by the patient's blowing upon a small diaphragm attached to the switch is sufficient to close it. The switch is easily actuated at distances up to 1 foot.

The puff-switch implemented by the RTI Team differs from previous puff-switches in that all movable parts are enclosed in a protective housing to make the unit

more durable in the hospital environment. The puff-switch was compatible with the commercially available nurse-call system in use at the Conway Nursing Center which permits communication between the nurse station and the patient by means of an intercom system; the push-button switch normally used by the patient was simply replaced by the puff-switch. The unit is currently in operation. (See Figure 16)

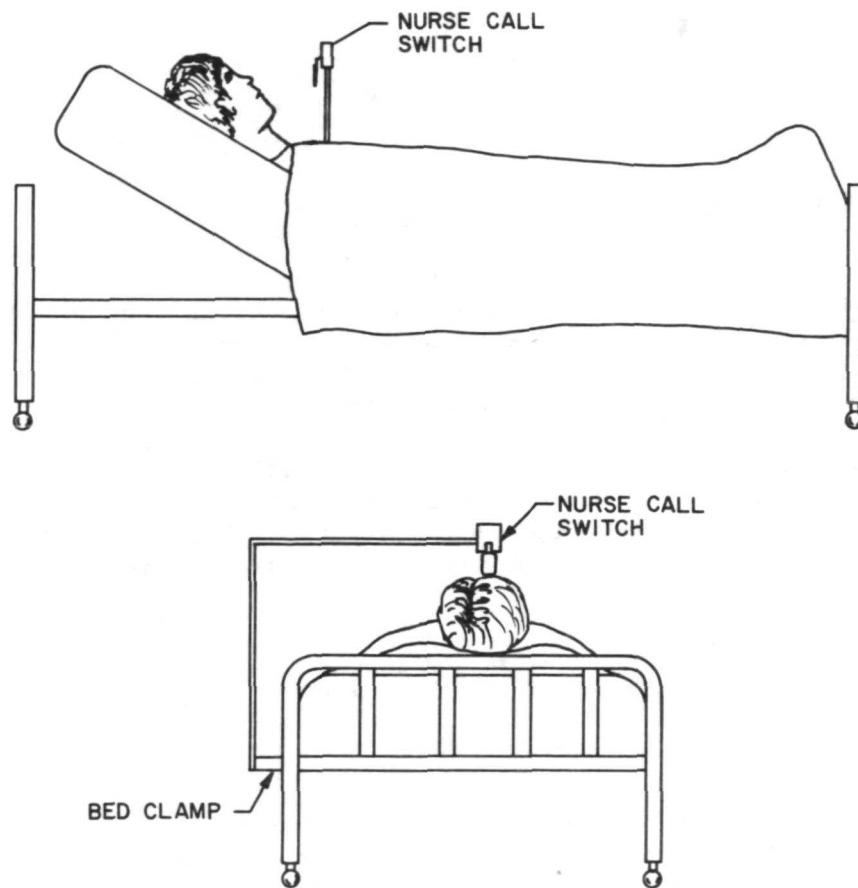


Figure 16. Nurse-Call Switch For Quadriplegic.

PROBLEM TU-36 *Analysis of Time Varying Spectral Analysis Data*

The major cause of illness in children from infancy through adolescence is respiratory disease of which the most serious forms include asthma, cystic fibrosis, and bronchitis. Significant research is being conducted both in the causes and cures of respiratory disease together with better methods for diagnosis of the diseases. The respiratory system consists of the lungs and a system of tubes or ducts that feed air into the lungs. Air proceeds from the nose and mouth through the trachea which is the central air duct. From this central tube two tubes diverge that eventually subdivide still further into smaller tubes called bronchial tubes. These bronchial tubes feed air into a section of the lung and each tube has a symmetrical counterpart in the other lung.

One useful and simple method to determine whether a portion of the lung is performing properly is to listen to the sounds made by air flow. Traditionally, this has been done with the stethoscope but only one section of the lung can be heard at one time unless the double stethoscope is used in which a separate chest piece is provided for each ear.

In biomedical problem TU-3, Lung Sound Analysis, the basic problem of further analysis of these pulmonary sounds was attacked. The problem is to analyze and display the sounds from the two sections of the chest wall in some graphical technique that will allow study of the amplitude, frequency, and time interval between the appearance of the sounds from various portions of the chest. The frequencies of interest are 50 to 10,000 hertz, and breathing rates are normally 25 breaths per minute in children although a range of 12 to 80 can occur. The amplitude of the sounds of interest is approximately 65dB to 30dB.

In the solution to biomedical problem TU-3 a real time spectral analysis system was developed which allowed a two dimensional display of pulmonary sounds in terms of the amplitude and frequency content of the sounds as they occurred. This information was then integrated over several breaths to provide the average spectral distribution for both inspiration and expiration for the sounds originating from a point on the chest. This provided the physician with a powerful tool for further analysis of pulmonary sound in order that the spectral distribution could be compared for both normal and diseased lung sounds.

Research conducted using this experimental apparatus revealed that although certain differences did occur in the time averaged spectral distribution of a diseased lung sound, it became apparent that subtle differences were being lost because of the averaging technique. For example, the appearance of a particular sound for a very brief period during the pulmonary cycle may well be a key to the detection of the disease, but in the case of average spectral density, the subtlety would be lost. Thus a means of recording and displaying the real time spectral density as a function of time was required.

In order to display the three dimensions of amplitude, frequency, and time, a 3D visual display was required. In Tech Brief 70-10030 a contourograph display system for monitoring electrocardiograms was described. This technique basically consisted of providing repeated traces of the electrocardiogram on a storage oscilloscope but each succeeding trace was displaced in the Y-direction so that repeated traces could be compared. This switching system required that a Z-axis input of the storage oscilloscope be blanked during the retrace and that the Y-axis be displaced by a fixed amount on each succeeding trace. It was clear that this technique could also be used for the display of real time spectral analysis data of pulmonary sounds.

A similar system was designed and built which allowed the three dimensional display of real time pulmonary sound data (see Figure 17). This system was installed and became operational in May 1973 and its value in detecting patterns with subtle variations became immediately obvious. The system is so designed that various frequency bands can be displayed with the amplitude in a variety of modes such as linear, log, and squared amplitude. The time axis can be varied in such a way as to display varying portions of the cycle and the spacing between successive traces can be varied as well as the skew angle of the retrace. This system is now operational and will be used for expanded research into the nature of pulmonary sounds.

The use of the 3D display is not unique to the NASA system although it has been effectively utilized in the aerospace community. Thus, this problem is being reported as an impact as opposed to a technology application. However, it should be noted that the impact on this research program has been considerable because of the information available through the NASA Biomedical Application Team program.

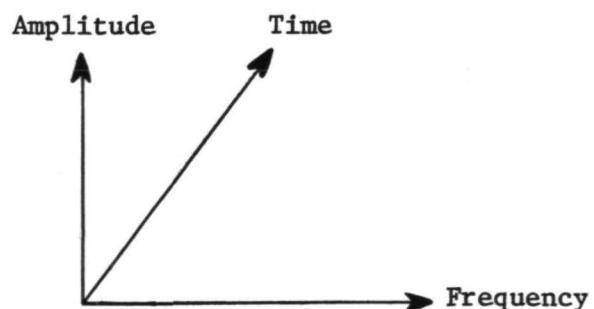
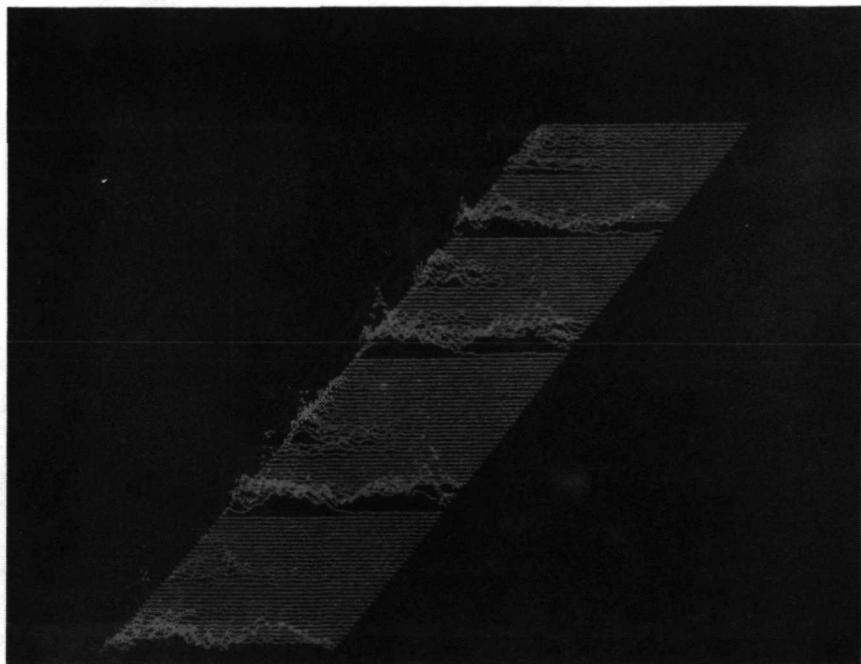


Figure 17. Spectral Density of Pulmonary Sound of Asthmatic Child

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3.0 SUMMARY OF TEAM ACTIVITY DURING REPORTING PERIOD

The following is a summary of project activity undertaken by the RTI Team during the period September 1, 1972, to August 31, 1973.

<i>New Problems Accepted</i>	39
<i>Problems Rejected</i>	10
<i>Problems Inactivated</i>	38
<i>Problems Reactivated</i>	1
<i>Total Problems Currently Active</i>	59
<i>Preliminary Problem Statements Prepared</i>	39
<i>Problem Statements Disseminated</i>	2
<i>Responses to Problem Statements</i>	12
<i>RDC Computer Searches Initiated</i>	22
<i>Impacts</i>	2
<i>Potential Technology Applications</i>	5
<i>Technology Applications</i>	7

A description of currently active problems categorized by health area is attached as Appendix B.

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4.0 APPLICATIONS ENGINEERING PROGRAM

Selected problems have been accepted for implementation of technology under the Applications Engineering Program. In the program, the technology is actually implemented by NASA. Activities for these 10 problems are presented in the following summaries.

PROBLEM DU-31 *Catheter-Mounted Pressure Transducer*

A pressure transducer developed for use in the aerospace program has been modified for measurement of pressure in human hearts.

Heart disease is the major cause of death among the American people. The disease affects every age group, and it is extremely interesting that the youngest age group, infants, demonstrates nearly all varieties of abnormal cardiac condition. Thus, the study of pediatric heart disease is of major importance. Many types of abnormal heart conditions in children can be surgically corrected, but proper diagnosis becomes of paramount importance. The correct diagnosis of heart disease in children requires very careful measurements of pressure and volume of the heart. The arteries and heart chambers are very small and require an unusually small catheter for making various measurements. One of the measurements of great importance is pressure in the aorta and in all four chambers of the heart. This pressure measurement is more difficult in small children because heart rates can range as high as 300 beats per minute. Thus, the pressure transducers must be able to measure rapid changes in pressure and very small gradients in pressure in order to detect the abnormalities in heart condition.

A major research effort at Duke University Medical Center is devoted to understanding the heart diseases in children. In particular, the research is devoted to determining a correlation between pressure changes in all four chambers of the heart with motions of the chest wall. The motions of the chest wall can be detected by an apex cardiogram. Thus, a correlation will be made between a measurement technique requiring penetration of the heart and a measurement technique entirely external to the body. It is necessary to measure pressure, but the existing methods of measuring pressure do not have sufficient sensitivity, frequency response, or size capability. Also, fluid-filled catheters, which are commonly used, cause significant overshoot in the contraction pressure waveform. Thus, a new pressure-measuring device is required.

A pressure transducer with size #5 French (1.5 mm) or smaller is required. The pressure range is -30 mm to +300 mm Hg. The maximum frequency of response is undetermined but frequencies as high as 100 Hz may be encountered. Pressure resolution of 1 mm Hg is required, and temperature compensation from 35°-40°C is required. The transducer should be mounted on the side of a catheter to prevent erroneous readings due to motion of the catheter against the heart wall.

The solution to this problem appears to be the tunnel diode transducer developed by Dr. W. Rindner at Electronics Research Center. Dr. Rindner has formed his own company, Device Research, Incorporated, and is presently offering the NASA-developed transducer. The Duke researcher has examined the specifications of the Rindner TD-1 Transducer and believes that this will solve his problem.

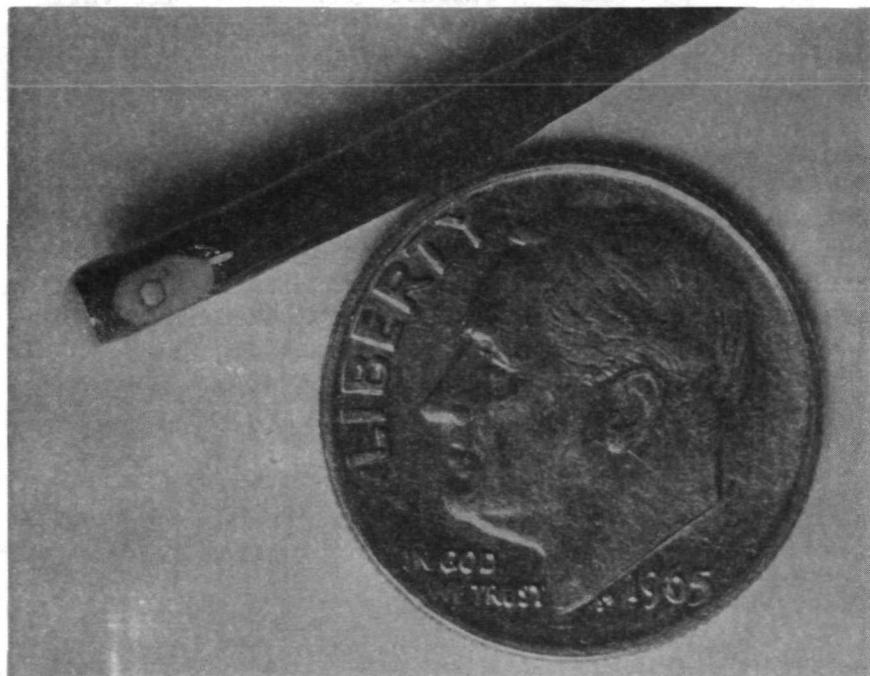


Figure 18. Tunnel Diode Pressure Transducer.

The TD-1 pressure transducer, shown in Figure 18 is presently undergoing tests at Duke University Medical Center to determine its characteristics in animal experiments. Initial tests indicated excellent sensitivity but some problems in thermal drift. Dr. Rindner is modifying the transducer to solve this problem.

PROBLEM DU-48 *Urine Flowmeter*

Diseases of the urinary system are significant medical problems. One of the problem areas concerns the ureters, i.e., the tubes that connect each kidney to the bladder. Urine-flow measurements in the ureter are being used in a research study to gain knowledge of ureteral physiology. Improved flow-measurement techniques also could be used in clinical studies of kidney, ureteral, and bladder diseases. All existing techniques for measuring flow in the ureter involve collecting samples of urine over definite intervals of time and calculating average flow rates. These average flow measurements are not satisfactory when the pulsatile nature of flow in the ureter is being studied. This pulsatile flow of urine is felt to be a very important factor in obtaining a better understanding of ureteral physiology.

The requirement here is for a technique that employs a transducer for measuring instantaneous rates of urine flow in the ureter. The transducer can be used either internally or externally. If an external transducer is used, the flow of urine can be diverted to a point outside the body using a catheter.

The flowmeter should measure transient urine flows of from 1 to 100 cc/min with an accuracy of ± 1 percent. Size of the flowmeter is not important because it can be outside the body. A flowmeter using the principle of thermal distribution developed for the Skylab flight program appears to be a potential solution to this problem but modifications in the Skylab device will be required. The NASA contractor building the Skylab device has agreed to build the modified device and an application engineering request has been approved by NASA Headquarters.

PROBLEM DU-74 *Testing of Neuropathic Patients*

A system designed to measure pilot performance will be adapted for the study of neuromuscular disorders.

Many people suffer neuromuscular disorders that result in the loss or impairment of muscular control. The cause of these disorders is damage to the nervous system that controls the musculature. One symptom of this disorder is uncontrollable contraction and relaxation of muscles.

Modern therapeutic treatment allows many thousands of patients to improve the degree to which they can exercise voluntary control over their muscles and, therefore, to assume a more active and useful role in society. Therapeutic treatment, however, is presently hampered by the difficulty of measuring the improvement that individual patients make during the course of therapy. As an example of a currently employed technique for measuring a patient's progress, the patient is presented with a drawing of a thin-lined geometrical pattern and is asked to trace the pattern with a pencil. From this experiment, one can make a subjective judgment regarding the degree to which a patient is able to control the movement of his hand. A more quantitative measurement of a patient's progress would lead to refined therapeutic techniques, which, in turn, should bring about more rapid and more complete recovery for the many patients suffering from neuromuscular disorders.

In the design of highly reliable and space systems that are to be operated under direct manual control, the problem of the man-machine interface becomes critical. Scientists at NASA's Langley Research Center (LRC) have been working for several years on the problems of designing flight vehicles that are well suited for control by a human operator. Of major importance is the understanding of the motor and perceptual characteristics of the human pilot. To measure pilot characteristics such as limb controllability, response time, rate of movement, etc., LRC researchers developed a variety of tests and testing apparatuses. This research resulted in a mathematical model of the human pilot.

The Team learned of this research at LRC and arranged a visit to talk with two of the pioneers in pilot modeling. Upon discussing this problem with the LRC researchers, it became evident that the tests they had devised to determine pilot characteristics had much in common with the requirements for testing patients with motor disorders. The Team was given a demonstration of a tracking task that was employed at LRC. In this case, aircraft pilots were required to track an oscilloscope trace of a noisy signal using a joystick manipulator. With this configuration, it was possible to record both pilot response and instantaneous error in tracking random disturbance. Included in the LRC tasks were control stick and aircraft dynamics. This configuration is illustrated in Figure 19 for a single-axis tracking task. The Langley researchers suggested that the stick and aircraft dynamics be removed from the tasks in order to acquire a better measurement of the motor performance of neuropathic patients. The LRC tracking unit with the suggested modifications as shown in Figure 20 has been evaluated by the problem originator.

The LRC system will provide much quantitative information on human motor performance; however, a modified version of the manipulator will be required to make the test results less sensitive to the patient's perceptual performance. Engineers at LRC are building a unit for administering and analyzing the results of tracking tasks which will be employed in a clinical environment at Duke University School of Medicine.

PROBLEM NCI-3 *Automatic Blood Pressure Measurement of Critically Ill Patients*

Equipment designed to monitor astronauts during ground training is being used in the monitoring of leukemia patients. Leukemia, a major form of cancer, is a disease characterized by a self-perpetuating proliferation of white blood cell forming tissue.

The National Cancer Institute (NCI) is conducting a vigorous program directed toward finding the causes and cure for this disease. In the clinical phase of this program, a problem exists in the early detection of shock, which is defined as a sudden reduction in the volume of circulating blood. Shock often occurs as the result of hemorrhage, infection, or a combination of the two; but if not recognized early, shock becomes irreversible and rapidly fatal.

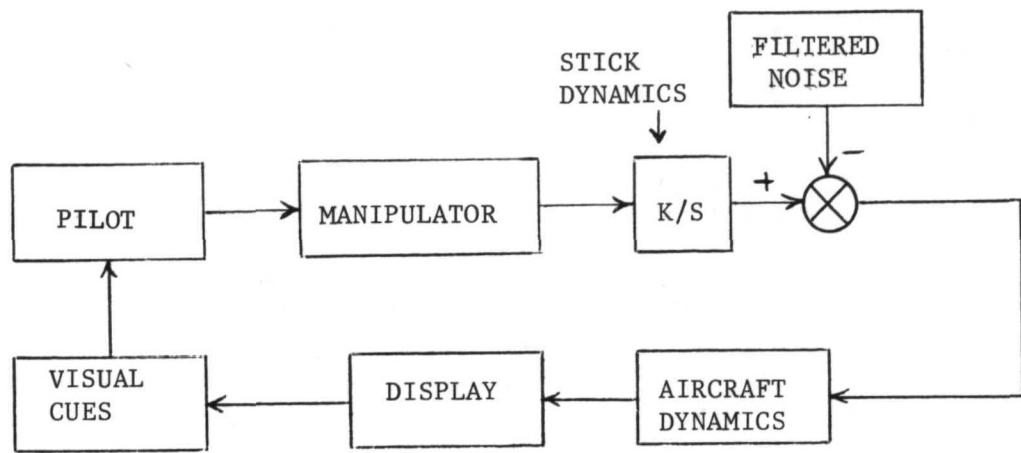


Figure 19. Single Axis LRC Tracking Task Block Diagram.

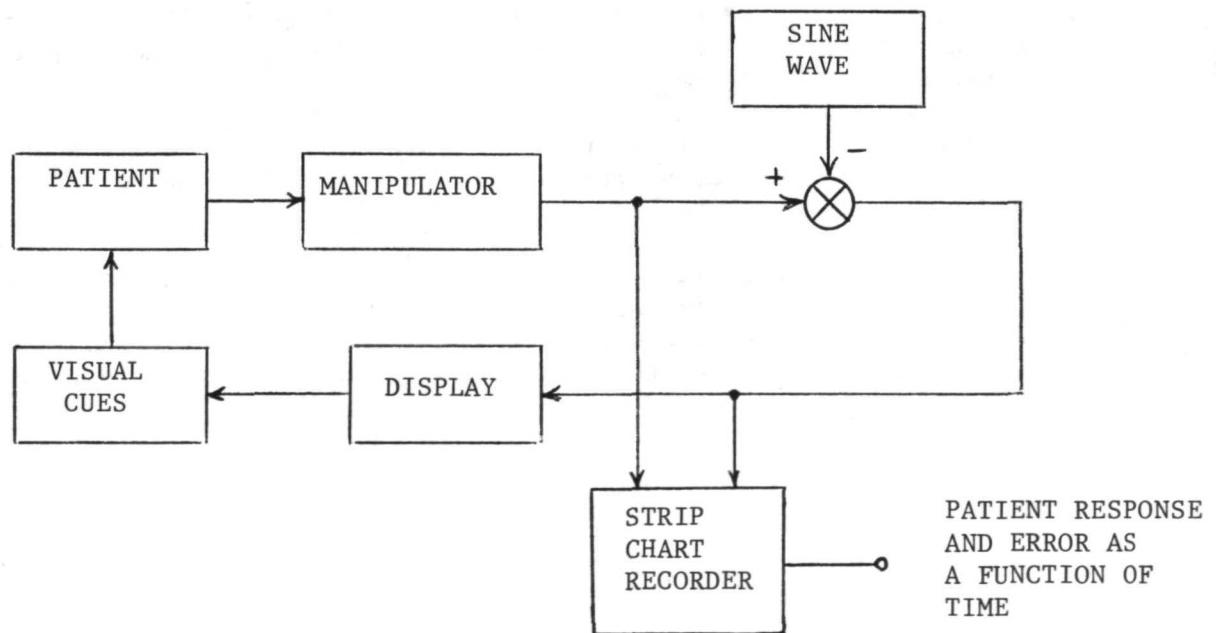


Figure 20. Block Diagram of Single Axis Track Task for Testing Neuropathic Patients.

Thus, a need exists for an accurate indicator of the onset of shock so that corrective measures can be taken.

One important measure of the onset of shock is a reduction in blood pressure. Blood pressure is defined as the pressure exerted by the blood within the arteries. The two pressures of interest, systolic and diastolic, are the maximum and minimum pressures exerted on the walls of the arteries by the pulsatile pumping of the heart.

The primary method for measuring blood pressure is the sphygmomanometer, which is a cuff placed around the upper arm. The cuff method is undesirable for continuous monitoring of blood pressure because the repeated inflation of the cuff disturbs the patient.

A method for monitoring blood pressure on a continuous basis is needed for bed patients. The method should not significantly disturb the patient. The pressure range of interest is 0-200 mm Hg and a sensitivity of 5-10 mm Hg is required. An invasive technique (i.e., one that punctures the skin) is considered undesirable.

A computer search of the NASA document file was made as the first step toward finding a solution to this problem. Although the search revealed a number of interesting documents, no adequate solution was found. However, the search revealed that Ames Research Center had conducted much of NASA's research in blood pressure measurement. During a trip to Ames Research Center, the Team discussed the problem with Mr. Joseph R. Smith who suggested that an alternate approach would be to use the oximeter developed by ARC for measuring blood oxygen content. This device was designed to clip into the upper part of the ear and measure the oxygen content of the peripheral blood during various ground testing operations such as centrifuging. This approach was discussed with the problem originator, and it was agreed that the approach was a useful one.

The oximeter, shown in Figure 21, operates by measuring the infrared absorption through the upper part of the ear by placing an infrared source and a detector on opposite sides of the ear.

The output of the meter is a measure of the oxygen in the blood of the ear. Since the constantly changing blood volume of the ear is caused by the blood pressure changes, the output of the oximeter is affected by changes in the blood pressure. Thus, the unit can be used to obtain a relative measure of blood pressure but not an absolute measure. The problem originator stated that the relative change in blood pressure was of major interest because it is this relative measure that is of importance in detecting the onset of shock. The problem originator also stated that tests needed to be conducted to determine whether the peripheral blood pressure could be used as an adequate measure of the onset of shock.

Initial tests on the device indicates drift problems due to the age of the instrument. An applications engineering request has been submitted to NASA Headquarters to build a new model of this device. It is anticipated that clinical evaluation of the new model will be performed at Duke University School of Medicine and Bowman Gray School of Medicine.



Figure 21. NASA Ear Oximeter.

PROBLEM NCI-4 Controlled Rate of Freezing a Liquid

Leukemia, a disease that kills about 15,000 Americans annually, is characterized by a proliferation of the tissue that forms white blood cells. Although the white cells in the blood can either increase, decrease, or remain constant in number, the bone marrow where the cells are formed will proliferate.

Treatment of leukemia involves killing the cancerous white blood cells in the blood and in the bone marrow using drugs or radiation. This process can cause loss of all bone marrow so that normal white cell production cannot occur.

When this loss of bone marrow occurs, white cells must be resupplied to the patient. For this purpose a bank or storage facility of white cells is required. This is impossible at present because adequate storage procedures are unavailable. Although red cells can be preserved by freezing, white cells are now destroyed by the existing freezing and thawing procedures. One important parameter in freezing white blood cells is believed to be the rate of freezing. Rate of freezing cannot at present be controlled because of the plateau in cooling rate when the latent heat is released at the freezing point.

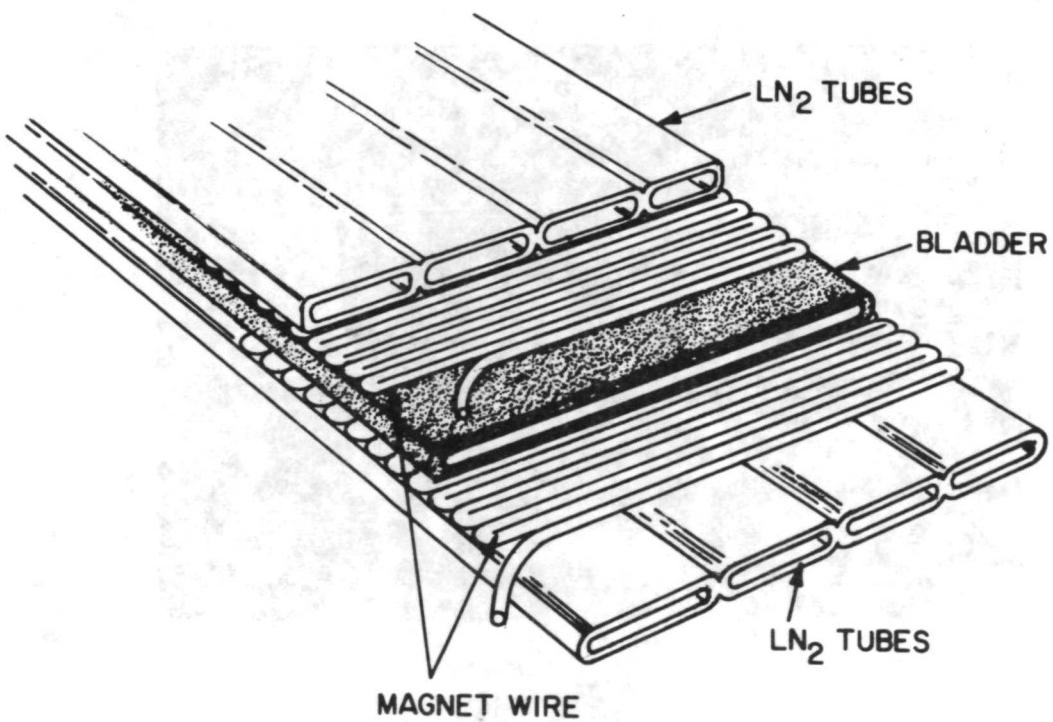


Figure 22. Controlled Freezing Unit.

The present method for freezing is a liquid nitrogen system, which cools a secondary liquid, which in turn cools the cells contained in a flat Teflon bag. To prevent contamination of the cells, it is desirable that any new technique utilize a Teflon container.

The basic requirement is to have a method of detecting the onset of freezing and then increasing the heat transfer rate during the release of latent heat so that a nearly constant rate of freezing can be maintained from room temperature to -50°C.

This problem was forwarded to the Jet Propulsion Laboratory (JPL) where Mr. L. S. Doubt and Mr. W. Tener suggested the configuration shown in Figure 22. The cells are held in a Teflon bladder, which is surrounded by a copper heating element and liquid nitrogen tubes. During the cooling cycle from room temperature to the freezing point, the heating coils control the cooling rate. At the freezing point, the heat is turned off and the latent heat of the cells is rapidly removed. Then the heat is turned on again to control the rate until -50°C is reached.

Although the proposed solution originated at JPL, implementation of this idea is being pursued by the Goddard Space Flight Center (GSFC) because of the geographic proximity of NCI and GSFC. GSFC personnel used computer aided design to optimize the basic configuration before hardware construction. The computer analysis utilized the same techniques that NASA uses in space applications such as thermal balance in spacecraft. Coordination between NCI and GSFC research staff members was closely maintained to insure that the final device met all medical and engineering requirements.

Initial studies showed that a minor modification of the initial concept was required. A computer simulation model was developed that allowed design modifications to be quickly evaluated. Following this phase, an experimental model of the design was built and successfully tested. It is anticipated that an improved model will be delivered to NCI during the fall of 1973.

PROBLEM VAM-6 *Negative Pressure Chamber*

Respiratory distress syndrome (also called hyaline membrane disease) is the major cause of death in the newborn. It is estimated that more than 20,000 babies succumb to this disease in the United States each year. Respiratory distress syndrome is a condition of the newborn in which the lungs are collapsed; it is thought to be due to the absence, because of immaturity, of an alveolar substance that decreases the surface tension and permits lungs reexpansion after each expiration.

Recently, researchers at several medical centers in the United States and Canada have produced encouraging results with the use of continuous positive airway pressure (CPAP) and continuous negative pressure (CNP) therapeutic techniques. The CPAP method makes use of an endotracheal tube which continuously forces oxygen-rich air into the lungs while the CNP method keeps the infant's lungs expanded by subjecting the chest to continuous negative pressure. The negative pressure

around the chest helps the infant to expand his lungs and to maintain the proper residual volume of air. If life can be sustained for 4 days by either method of treatment, the missing surfactant will become present in a sufficient quantity for normal breathing to occur.

The CNP method has been employed by specialists at the University of Miami School of Medicine who were among the first to make use of the technique. A commercially available respirator was modified to produce a constant negative pressure and has proven successful in saving the lives of several infants. The University of Miami researchers, Dr. Akram Tamer and Dr. Eduardo Bancalari, recognized several shortcomings in their present system and requested assistance from the RTI Biomedical Application Team. The disadvantages of the present system are:

(1) High cost because it is equipped with an electronic cycling system (for controlled breathing), which is not necessary in the continuous negative pressure technique.

(2) The negative pressure is applied to the entire body except the head, thus interfering with the infant's cardiovascular function and producing an increase of air in the gastrointestinal tract.

(3) The nursing care of the infant is very difficult and cannot be given without discontinuing the negative pressure.

To overcome these disadvantages, the University of Miami medical team wished to fabricate a CNP chamber that would cover only the infant's thorax, arms, and upper abdomen. Such a system would offer the following advantages over the use of continuous positive pressure in the airway:

(1) It avoids tracheal intubation and leaves the face free for nursing care. This point is of great importance since, in addition to feeding the infant, it is normally necessary to suck mucus from the infant's trachea at frequent intervals. The CPAP must be discontinued during such nursing care.

(2) Its interference with venous return to the right heart will be minimal.

(3) It avoids the increase of air in the gastrointestinal tract.

The technology employed in the construction of the Lower Body Negative Pressure System (Figures 23 and 24) for NASA's 1973 Skylab mission has direct application in providing therapeutic treatment for respiratory distress syndrome. A Marshall Space Flight Center (MSFC) engineer, Mr. Ted Knowling, visited the University of Miami medical team to consider the applicability of the NASA Lower Body Negative Pressure System to this problem. The major problem to be encountered in the design of the needed

CNP system is the air seal that will be required at the waist. (The neck seal that is used on commercially available respirators is thought to be adequate.) The waist seal that was designed for NASA's Lower Body Negative Pressure System appears to provide an excellent solution to the problem of sealing the CNP unit at the infant's waist. Additionally, the NASA seal is adjustable, which will allow the CNP chamber to accommodate infants of various sizes.

A mechanical designer from the University of Miami visited Mr. Ted Knowling at MSFC during August 1972. A preliminary design for the CNP system was worked out at that time. The Department of Biomedical Engineering at the University of Miami plans to fabricate the CNP unit and NASA Headquarters has approved an applications engineering request.

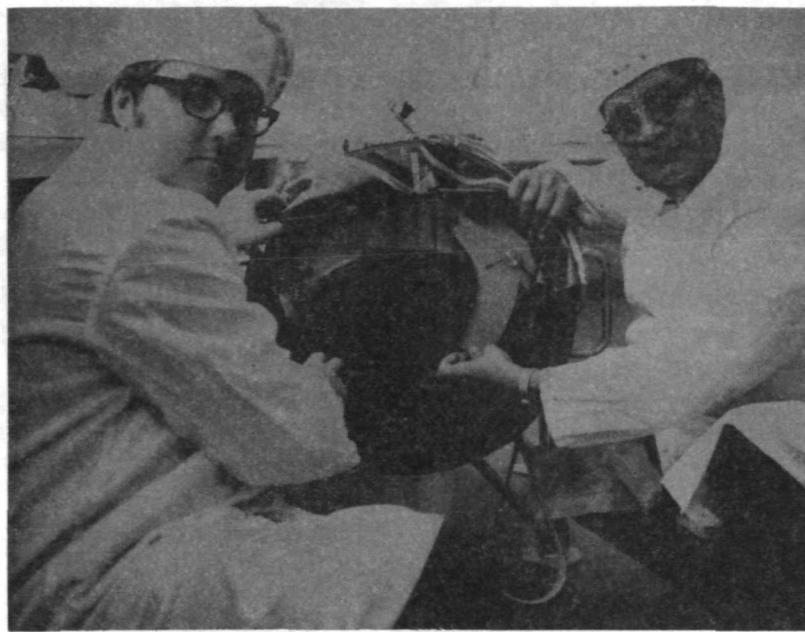


Figure 23. NASA Lower Body Negative Pressure Chamber Seal.

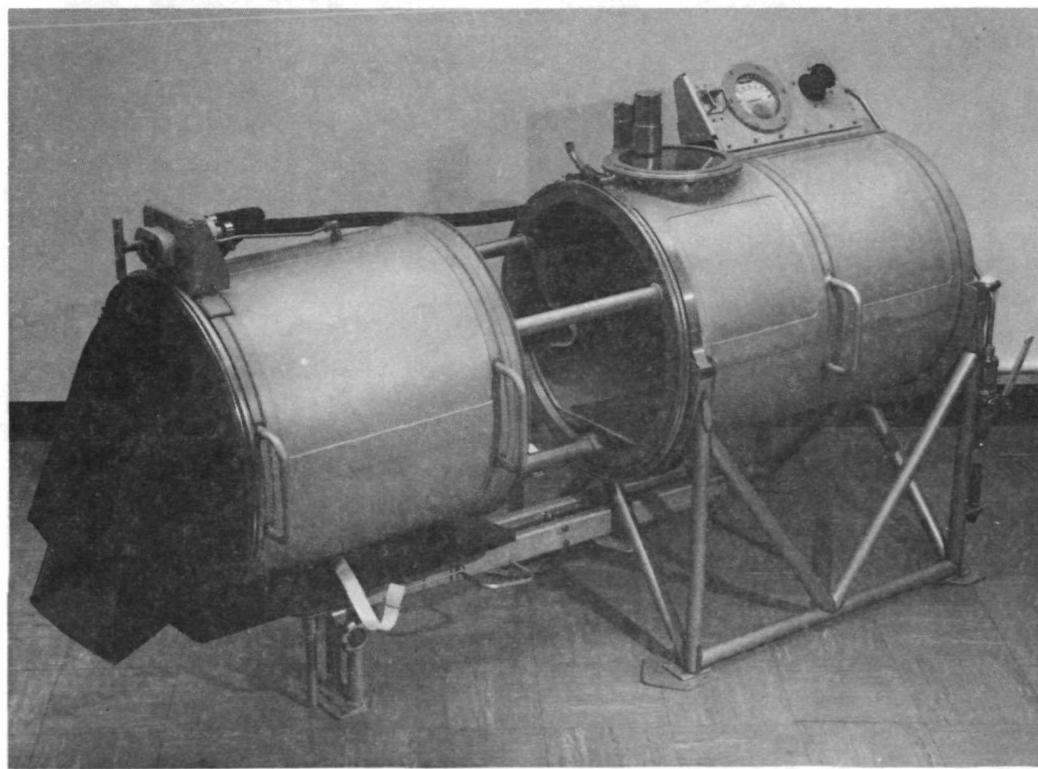


Figure 24. NASA Lower Body Negative Pressure Chamber.

PROBLEM VAM-7 *Bacteria Detection Using Fluorescent Labelling*

Researchers at the University of Miami have identified a type of bacteria that causes tooth decay in laboratory animals. This bacteria has now been found in human beings and is possibly a major cause of tooth decay in man. Fluorescent techniques are employed to discover the presence of this bacteria in human beings. This is possible because of the development of a vaccine that makes laboratory animals produce antibodies to attack the bacteria. These antibodies are labeled with a substance (fluorescein thiocyanate) that makes them fluoresce when excited with ultraviolet light. When the labeled antibodies are applied to a culture having these bacteria, they become bound to the cell wall of the bacteria. The culture is then washed and only those antibodies that are bound to the bacteria remain. Therefore, when the culture is viewed under a microscope using ultraviolet illumination, the antibodies can be spotted, thus signifying the presence of the bacteria that cause tooth decay.

To find out how many of these bacteria are present, all bacteria in the culture are allowed to grow. It was discovered that a second type of bacteria that normally resides in the mouths of human beings exhibits a natural fluorescence. The autofluorescence of the second bacteria complicates the detection of the labeled antibodies. It should be emphasized that the autofluorescence presents a problem only when all bacteria are allowed to grow (i.e., it is only when the autofluorescing bacteria are in colonies that the autofluorescence is of sufficient intensity to be observable). A means of suppressing the radiation due to autofluorescence is needed.

Mr. Larry Dunkleman of Goddard Space Flight Center visited the problem originator and conducted a preliminary investigation of the problem during March of 1972. The problem originator has sent bacteria samples to GSFC for analysis.

PROBLEM VAM-16 *Transmission of Gamma Camera Data*

NASA's communications technology is being employed to design a data transmission system for transmitting gamma camera data from remote hospitals into a university medical center for analysis.

Radioisotopes can be administered harmlessly to a patient if the dose is kept small; thus they have found use in a variety of medical diagnostic and research applications. Radioactive gallium, for example, concentrates in a variety of human neoplasms and is of great assistance to the clinician in locating tumors otherwise difficult to find. A second example of the application of isotopes is the use of a radioactive dye in the heart to aid in the diagnosis of heart ailments. One of the instruments commonly used to detect and image a region of radioactivity is the gamma camera. Gamma camera data is well suited for digital processing (e.g., image enhancement, organ volume and blood flow rate computations, etc.) thus making the gamma camera data of increased diagnostic aid to the physician.

Medical specialists, computing facilities as well as engineering support capable of processing and analyzing the gamma camera data to increase its diagnostic value are available at only a small number of medical centers across the United States. Gamma cameras, however, are available for taking patient data at many hospitals. Such is the case in the Miami area. Hospitals in the Miami area rely upon the medical staff at the University of Miami School of Medicine to provide competent consultation on a variety of medical problems. Gamma camera data can be taken at remote hospitals but it cannot be adequately analyzed without the University's medical and technical staff. The Department of Nuclear Medicine wishes to design a data transmission system for transmitting gamma camera data from remote hospitals to the University's medical center.

The problem originator visited MSFC to discuss the problem in detail. An engineer from MSFC visited the University medical center and began a systems engineering analysis of the communication requirements for this application.

PROBLEM WF-3 *Prosthetic Valve for Urinary Tract*

A number of different injuries and diseases can result in loss of control of urinary function. Victims of congenital defects, neurogenic bladder diseases, stroke, and multiple sclerosis, as well as war and automobile accident casualties, frequently experience bladder and urethral malfunctions. These malfunctions usually involve an inability to contract the muscles in the bladder wall or an inability to relax muscles that close the urethra; i.e., the passage through which the bladder is emptied. This condition generally results in gradual deterioration of the bladder, infections of the urinary tract, and, in some cases, damage to the kidneys and subsequent death. This condition is the most frequent cause of death of paraplegics. In treating patients who cannot control urinary function, it is important that the bladder be allowed to fill and then be emptied rapidly every 3 to 4 hours. This periodic functioning allows the muscles of the bladder to be exercised and, as a result, to remain healthy. One approach that has been taken is to attach electrodes to the bladder muscles so that contraction of the bladder can be electrically induced by the patient. This electrical stimulation unfortunately also induces contraction of muscle groups--i.e., sphincters--that close the urethra. As a result, fluid pressure inside the bladder becomes dangerously and painfully high.

A valve that can be implanted in the urethra and can be controlled by the patient is needed to successfully treat the loss of urinary function. In cases where bladder muscle is healthy when the valve is implanted, the bladder would contract when the valve is opened without stimulation due to the inherent elasticity of healthy muscle tissue. If bladder muscle deterioration has occurred, electrical stimulation can be used simultaneously with opening of the valve without causing excessive internal pressure.

Functional requirements and constraints on the configuration of the prosthetic urethral valve are as follows:

(1) It is desirable that the valve be cylindrical with a maximum length of 2 cm and a maximum diameter of 2.5 cm. (Small rigid tubes will pass through the physiological valves--sphincter vesicle and external sphincter--shown in Figure 25 so that fluid is held in the bladder only by the prosthetic valve.)

(2) The patient must have manual control of the valve.

(3) The valve must remain closed when exposed to a maximum differential pressure of 150 cm of H₂O.

(4) The valve cannot be controlled through the use of wires or tubes passing through the skin.

(5) All surfaces of the valve that are exposed to tissue must be physiologically inert material, such as silicone rubber.

(6) Functional reliability is an absolute necessity.

The solution to the requirement for a prosthetic urethral valve (Figure 25) is a completely implanted and closed hydraulic system with two stable states. One state corresponds to the valve being closed; in the other state, the valve is open. The open and closed states of the prosthesis are selected by the patient. This is done simply by pressing with the hand on one of two positions of his body. A more detailed description of the operation and construction of the valve is presented in the following paragraphs.

The valve essentially consists of three elements: the urinary valve, a check valve, and a pressure bulb, connected by flexible tubing. The urinary valve consists of an inflatable, rubber diaphragm fitted into a polystyrene tube. The polystyrene tube restrains the diaphragm, so that, when the diaphragm is inflated, the tube is completely sealed. In addition, the polystyrene tube is configured to allow the urethral valve to be securely attached in place.

The check valve, which lies between the urinary valve and the pressure bulb, serves two functions. First, it is a one-way check valve placed so that, when the urethral valve diaphragm is inflated, the check valve is closed, pressurizing the diaphragm and keeping the urethral valve closed. Second, the check valve is specially designed so that slight deformation of the check valve, achieved by applying a small force to the body of the valve, causes the check valve to open. This releases pressure in the diaphragm opening the urethral valve. The body of the check valve is constructed from silicone rubber with a rigid ball preloaded on the seat. Slight pressure applied to the body of the check valve deforms the valve seat so that, instead of having a circular cross section, which can be sealed by a ball, it becomes an essentially elliptical cross section through which fluid can leak around the ball, releasing pressure on the urethral valve.

The pressure bulb is used to apply pressure to the diaphragm of the urethral valve, thus closing it. Both the check valve and the pressure bulb can be implanted beneath and operated through the skin on the patient's side. The two are separated by a flexible tube approximately 4 inches long to achieve unambiguous separation of function.

This system fulfills all of the requirements of the desired prosthetic urethral valve, yet retains a simplicity which should lead to reliable operation. Several features of the valve are particularly important: (1) The entire system can be easily coated with silicone rubber and rendered physiologically inert. (2) No external connections are required to actuate the valve. The simplicity of the check valve permits voiding using only the pressure of one finger on the skin at the appropriate point. Reinflation of the diaphragm, when voiding is complete, is easily accomplished by pressing with the palm of the hand over the bulb, which is implanted underneath the skin. (3) Because of the simplicity of the system, it should be a highly reliable device. Should the system fail, resulting in loss of pressure to the prosthetic urethral valve, the urinary track would remain open. Thus an immediate emergency operation would not be required, as would be the case if the valve could fail in a closed position. (4) Inflation and deflation of the diaphragm in the urinary valve will result in flexing of the exterior surfaces of the valve that come in contact with the urine. This flexing action will tend to break off any incrustation that might occur, keeping the closing surfaces of the valve clean.

The prosthetic urethral valve has been fabricated under NASA contract by the Biomedical Engineering Department of the University of Virginia. A total of five units were completed. Arrangements have been completed with members of the University of Virginia Medical School for *in vivo* testing of the valves in experimental animals.

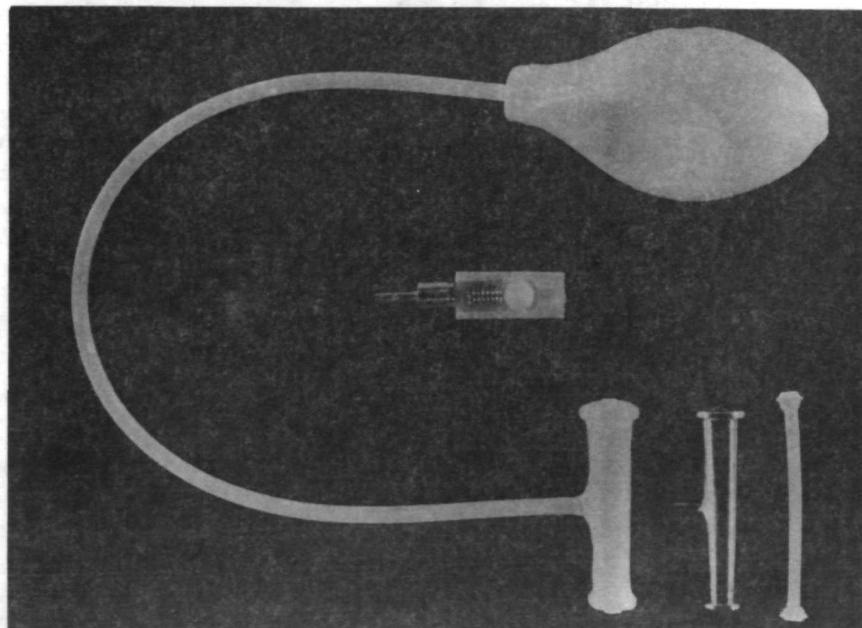


Figure 25. Prosthetic Urethral Valve.

PROBLEM WWRC-7 A Signaling (Nurse-Call) System for Multiple Sclerosis Patients

A NASA engineer has designed a call system for multiple sclerosis patients which is being evaluated in a major rehabilitation center.

The Woodrow Wilson Rehabilitation Center (WWRC) of the Virginia Department of Vocational Rehabilitation is planning a new building for the Medical Services Division. Among those who will be housed in the new building are a number of multiple sclerosis patients with severe disabilities. Such patients have little or no use of hands or feet. Consequently, they must depend on the services of nurses for practically all of their needs. Their disabilities are often so severe that they cannot accomplish the relatively simple task (for a person without disability) of operating the call button used in most hospitals to initiate a signaling system.

The patients requiring such a signaling system generally have voluntary control of one or all of the following functions that could conceivably be used for control:

- (1) Breath (respiration)
- (2) Eye movement and blink
- (3) Head motion--the head can generally be raised 2 inches and can be turned from side to side.

Most patients cannot change their positions except for the head so that they remain essentially stationary unless moved by attendants. It is desirable that the signaling system be capable of activation by a patient sitting in a wheelchair beside the bed. Generally, complicated electronic and optical systems of high sensitivity that require frequent adjustment or maintenance are undesirable because of the lack of skilled technicians. On the other hand, if an electronic or optical system of great ruggedness and high reliability could be achieved, it would certainly be given consideration. In summary, a system capable of operation by one of the three control mechanisms available to the patient is required, but ease of maintenance and high reliability cannot be ignored as constraints on this problem. The Southwest Research Institute (SwRI) Team has been working for some time with the Marshall Space Flight Center and the Langley Research Center on a device to permit paraplegics to perform a number of functions from their beds. The system that is being developed employs a breath-actuated switch suggested by personnel at the Langley Research Center along with a logic circuit that permits the patient to control a number of electrically operable devices from his bed. The system being developed for the application identified by the SwRI Team is more complex than that required by the problem at WWRC. The problem at WWRC is merely to call the nurse and, essentially, a substitute for the hand-activated nurse-call button is required.

(See Figure 26). At WWRC a commercially available unit is used to permit communication between the nurse station and the patient by means of an intercom system. The system is activated by a call button. Although the problem at WWRC does not require the complexity of that required at SwRI, the breath-operated microswitch suggested by LRC as the control element for the more complex system can be used in conjunction with the commercially available system at WWRC. The Langley breath-actuated switch appears to be completely compatible with the current installation at WWRC. This, of course, is a very significant advantage. One of the breath-actuated switches has been obtained for evaluation at WWRC. Should the evaluation prove that the breath-actuated switch is a viable solution to the problem, it is anticipated that WWRC will convert all multiple sclerosis and paraplegic call stations to the use of the breath-actuated microswitch.



Figure 26. Breath-actuated Switch.

5.0 CONCLUSIONS AND RECOMMENDATIONS

During this reporting period, four potential technology applications and seven technology applications were accomplished. The source of the solution to these problems came primarily from direct interaction between NASA personnel and Biomedical Application Team personnel. Seven of the problems were solved by direct contact with NASA personnel and four problems were solved as a result of problem statement circulation. This is the first annual reporting period since the inception of the Team in 1966 in which no problems were solved using literature searching. For the past 3 years direct interaction with NASA personnel and problem statement circulation have accounted for approximately 90 percent of the solutions to problems, but usually a small percent is solved using the computerized literature search. Because of the statistically small sample, one should not conclude that information searching is no longer productive but, as in past reporting periods, it contributed relatively little to the Team's total success.

In order for a technology application to be accomplished, implementation of the technology must occur. The means of implementation varies with each problem but for the 11 technology applications and potential technology applications reported during this period, the sources have been either expenditure of funds by the problem originator or NASA equipment loan. Thus, for this particular reporting period, the use of applications engineering funds was not required to implement the solutions to these problems. However, as noted in Section 4 of this report, several applications engineering projects are now underway utilizing NASA applications engineering funds. The availability of these funds remains a useful alternative in those cases where the requirements for applications engineering expenditures are met.

One of the valuable lessons learned by the Team since 1966 concerns the need for personal interaction by Team members with medical investigators and NASA personnel. One of the major reasons for success of the Biomedical Application Team Program is the active mode used by the Team in problem solving and maximum success comes when the Team is truly active. This requires that the Team travel to medical institutions and to NASA field centers. In addition to a heavy travel schedule, the Team must make maximum utilization of all other communication methods necessary to stimulate the technology transfer process. The future success of the Biomedical Application Team Program will require continued emphasis on the personal interaction process.

Another vital lesson learned in this program concerns the need for fast action by everyone associated with the program. When fast action occurs, the probability of a problem solution is significantly enhanced. A good example of this situation is the potential technology application

NCI-13, Portable Isolation Unit. In this problem the Team was able to provide the National Cancer Institute with technical information and a Biological Isolation Garment within 3 weeks. The National Cancer Institute personnel responded quickly and were able to build a prototype in less than 3 months from the time of initial contact with the Team. Delays in any phase of the transfer process will inhibit the probability of problem solution.

When a technology application has been accomplished, a problem has been solved for a single medical investigator. If this technology application is to have full impact on society, the technology should be available to other medical groups. This availability can be directly achieved if a manufacturer for the technology can be found. The problem of finding suitable manufacturers for completed technology applications is a major one which the Team has attacked in two ways. One way is direct interaction with certain industries, and the second way is through the formation of the Aerospace Technology Committee of the Association for the Advancement of Medical Instrumentation. Through these activities the Team has learned that it is extremely difficult to approach a large company with a prototype device with the expectation that the company will eventually manufacture the device. Efforts in this direction have largely failed. The major interest in this type of activity comes from the small entrepreneurial companies that are aggressively seeking new product opportunities. In order to approach a major corporation, it will be necessary for the Team to approach that company early in the problem definition phase. This will insure that the Team is considering problems of interest to the company. The validity of this approach has been demonstrated previously in those cases where problems have been solved for medical investigators at the National Institutes of Health who are utilizing the services of industrial contractors. The expansion of this mode of problem solving should enhance the total impact of the Biomedical Application Team Program.

APPENDIX A
PROJECT ACTIVITY SUMMARY

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TECHNOLOGY APPLICATIONS ACCOMPLISHED

- TU-3 *Lung Sound Detection*
MISC-27 *Improved Cushioning Material for Protective Helmets*
TU-29 *Damage to Blood from Microwave Heaters*
VAM-2 *Diagnosing Gait Abnormalities*
VAM-13 *Corrosion and Fracture of Orthopedic Implants*
WF-114 *Improved Utilization of Laboratory Computers*
WWRC-11 *A Valve for Leg Bag Urinals*

POTENTIAL TECHNOLOGY APPLICATIONS IDENTIFIED

- NCI-13 *Portable Isolation Garment*
TU-33 *Silica Measurement in Microgram Quantities*
UNC-73 *Image Intensifier for Microscopes*
WF-116 *Organ Preservation*

IMPACTS

- MISC-29 *Nurse-Call for Quadriplegic*
TU-36 *Analysis of Time Varying Spectral Analysis Data*

APPLICATIONS ENGINEERING ACTIVITIES

- DU-31 *Catheter-Mounted Pressure Transducer*
- DU-48 *Urine Flowmeter*
- DU-74 *Testing of Neuropathic Patients*
- NCI-3 *Automatic Blood Pressure Measurement of Critically Ill Patients*
- NCI-4 *Controlled Rate of Freezing a Liquid*
- VAM-6 *Negative Pressure Chamber*
- VAM-7 *Bacteria Detection Using Fluorescent Labelling*
- VAM-16 *Transmission of Gamma Camera Data*
- WF-3 *Prosthetic Valve for Urinary Tract*
- WWRC-7 *A Signaling (Nurse-Call) System for Multiple Sclerosis Patients*

CURRENTLY ACTIVE PROBLEMS AS OF 31 AUGUST 1973

<u>Problem Number</u>	<u>Status Code*</u>	<u>Problem Title</u>
CP-3	E	Automated Measurements from Coronary Angiograms
DU-31	E	Catheter-Mounted Pressure Transducer
DU-48	E	Urine Flowmeter
DU-74	E	Testing of Neuropathic Patients
EU-12	E	A Rapid Method of Applying EEG Electrodes
IPI-1	B	Beat-to-Beat Heart Rate Monitor
IPI-3	B	Eye Movement of Disturbed Children
IPI-4	B	Detection of Guppy Embryo Motion
MISC-20	B	Visual Field Mapping
MISC-23	B	Pattern Recognition of Ultrasonograms
MISC-24	D	Metal pH Electrode
MISC-25	D	Micro-Connector for Magnetically Guided Catheter
MISC-30	B	Food Dispensing System
MISC-32	B	Selective Permeable Membranes
MS-4	B	Early Detection of Obesity
MS-7	B	Energy Expenditure Measurement
NCI-3	F	Blood Pressure Measurement
NCI-4	E	Controlled Rate of Freezing a Liquid
NCI-9	E	Improved Emulsion for Autoradiography
NCI-10	C	Scanning Tumors in Small Animals with Gallium-67
NCI-12	B	New or Improved Methods of Detecting Breast Cancer
NCI-13	E	Portable Isolation Unit
TU-3	F	Lung Sound Detection
TU-9	E	Human Voice Analysis
TU-10	E	Quantization of Heart Tissue Hardness
TU-22	E	X-Ray Microplanigraph
TU-35	C	Subcutaneous Temperature and Power Density Measurement in a Microwave Field
TU-36	F	Analysis of Time Varying Spectral Analysis Data
TU-38	B	Portable Dialysis Unit
TU-39	B	Respiratory Neck Seal

*See explanation of status codes at end of listing.

<u>Problem Number</u>	<u>Status Code*</u>	<u>Problem Title</u>
UNC-63	D	<i>EKG Processor</i>
UNC-66	D	<i>Determining Tissue Perfusion Adequacy</i>
UNC-67	D	<i>Noninvasive Technique for Detecting Heart Valve Deterioration</i>
UNC-70	D	<i>Tantalum Suspension Creation and Delivery System</i>
UNC-71	D	<i>Finger Joint Flexor</i>
UNC-72	D	<i>Retractable Cover for Specimen Catheter</i>
UNC-73	E	<i>Image Intensifier for Microscopes</i>
UNC-74	A	<i>Remote Health Clinic Communication System</i>
UNC-75	A	<i>Improved Antigen Assay Sensitivity</i>
UNC-76	A	<i>Blood Pressure in a Rat's Tail</i>
UNC-78	A	<i>Platelet Aggregation Detection in Whole Blood</i>
VAM-2	F	<i>Diagnosing Gait Abnormalities</i>
VAM-6	D	<i>Negative Pressure Chamber</i>
VAM-7	D	<i>Bacteria Detection Using Fluorescent Labeling</i>
VAM-12	E	<i>Blood Pulse Rate Indicator</i>
VAM-13	F	<i>Corrosion and Fracture of Orthopedic Implants</i>
VAM-14	B	<i>Gas Concentration System</i>
VAM-15	B	<i>Cooling of Metals Under Electron Bombardment</i>
VAM-16	D	<i>Transmission of Gamma Camera Data</i>
VAM-17	B	<i>Automated Stereo Photographic Mapping</i>
WF-3	E	<i>Prosthetic Valve for Urinary Tract</i>
WF-88	E	<i>Accurate Determination of Arterial Pressure Pulse Transit Time</i>
WF-107	D	<i>An Inexpensive Method of Monitoring Respiration in Anesthetized Primates Being Ventilated by Mechanical Respirators</i>
WF-112	B	<i>Method of Correlating Composition with Differences in Surface Morphology of Kidney Stones</i>
WF-115	D	<i>A Means of Detecting the Onset of Shock</i>
WF-116	E	<i>Organ Preservation</i>
WF-117	B	<i>Blood Flow Measurement Via Thermal Dilution</i>
WWRC-7	E	<i>A Signaling (Nurse-Call) System for Multiple Sclerosis Patients</i>
WWRC-11	F	<i>A Valve for Leg Bag Urinals</i>

STATUS CODE DEFINITIONS

A. Problem Definition

Problem definition includes the identification of specific technology-related problems through discussions with biomedical investigators and the preparation of functional descriptions of problems using non-disciplinary terminology.

B. Information Searching

Information relevant to a solution is being sought by computer and/or manual information searching.

C. Problem Abstract Dissemination

An information search has revealed no potential solutions, and a problem abstract is being circulated to individual scientists and engineers at NASA Centers and contractor facilities to solicit suggestions.

D. Evaluation

Potentially useful information or technology has been identified and is being evaluated by the Team and/or the problem originator.

E. Potential Technology Application

Information or technology has been evaluated and found to be of potential value but has not been applied.

F. Followup Activity

A technology application has been accomplished, but further activity (e.g., documentation, obtaining experimental validation of utility, continuing modification, etc.) is required.

Health problems and needs

APPENDIX B

DESCRIPTION OF CURRENTLY ACTIVE PROBLEMS (CATEGORIZED BY HEALTH AREAS)

(This description does not include those active problems previously discussed in Section 2 as technology applications, potential technology applications, and impacts or in Section 4 as an applications engineering project.)

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HEALTH AREAS

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REHABILITATION MEDICINE	B-6
ORGAN ASSIST DEVICES	B-7
MENTAL HEALTH	B-7
DETECTION AND TREATMENT OF HEART DISEASE	B-8
DETECTION AND TREATMENT OF CANCER	B-13
ECOLOGY	B-18
REMOTE HEALTH CARE SERVICES	B-19
KIDNEY DISEASE DETECTION AND TREATMENT	B-19
REDUCTION OF INFANT MORTALITY	B-20
RESPIRATORY DISEASE DETECTION AND TREATMENT	B-21
IMPROVED SURGICAL PROCEDURES	B-22
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BASIC MEDICAL RESEARCH PROBLEMS	B-24
OTHER, MISCELLANEOUS	B-29

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MULTIPHASIC HEALTH SCREENING, CLINICAL DIAGNOSIS

PROBLEM MISC-20 *Visual Field Mapping*

The National Institute of Occupational Safety and Health (NIOSH) is concerned with assessing visual requirements and visual degradation associated with various occupational groups. One of the most important factors is the determination of the visual field: the part of the external world that is seen by the eye when its gaze is fixed. The visual field (for white light) of the normal eye subtends an angle of about 160° in the horizontal and 145° in the vertical meridian. Obviously, potential safety hazards exist if one's visual field is not compatible with his occupational environment. While the visual field narrows with age, it is suspected that certain occupational groups may experience more rapid degradation in their visual field because of their working environment.

Perimetry is the term applied to the procedure of mapping out the visual field. The instrument employed is called a perimeter. Perimeters currently in use are capable of determining major limitations of the visual field but are not suitable for mass screening in order to assess the occupational factors that contribute to changes in the visual field.

The problem originator is presently reviewing specifications on a vision tester developed for NASA under the IMBLMS program.

PROBLEM VAM-14 *Gas Concentration System*

The Department of Nuclear Medicine at the University of Miami is presently installing a cyclotron. One of the benefits to be derived from the cyclotron is the production of various radioactive gases. In particular, they will produce radioactive O₂, CO₂, CO, and N₂. Such radioactive gases have very short half-lives--often on the order of 20 seconds. This permits radiographic studies to be done while incurring a minimum radiation hazard. These gases will be piped to various locations within the hospital. It will be necessary to dispose of the unused gas. While it is possible to allow the unused gas to escape into the atmosphere, the Department of Nuclear Medicine feels that the best approach is to convert the gaseous waste into a liquid waste through a gas concentration system.

A search of the aerospace literature has resulted in some potentially useful information which is under evaluation by the problem originator.

PROBLEM VAM-15 *Cooling of Metals Under Positron and Deuteron Bombardment*

Improved techniques are needed for cooling metals that are bombarded by high intensity positron or deuteron beams during the process of generating radioactive materials. A cyclotron is presently being installed at the Mount Sinai Hospital of Greater Miami. The cyclotron will produce a variety of radioactive

materials which will be employed to conduct radiographic studies as well as to provide radiation therapy for patients. Materials are made radioactive by bombarding them with a positron or deuteron beam. A given metal produces a specific radioactive element. The bombardments cause very high temperatures to exist in the metal in the vicinity of the beam. It is necessary to find a means of dissipating this heat. Contact with a metallurgist at Langley Research Center has been established.

REHABILITATION MEDICINE

MISC-30 *Food Dispensing System*

Many people suffer neuromuscular disorders that result in the loss or impairment of muscular control. The cause of these disorders is damage to the nervous system that controls the musculature. One symptom of such disorders is the uncontrolled contraction and relaxation of muscles. Patients without voluntary control of their movements depend upon the services of others for practically all of their needs. In recent years a number of devices have been constructed in an attempt to make such patients more self-reliant. Making patients more self-reliant will contribute greatly toward reducing the size of the nursing staff required to care for handicapped persons and will give patients a physiological boost which will enable them to better cope with their disability. One very important area that has received little previous attention is that of enabling a patient who cannot exercise voluntary control of his limb movements to feed himself. Fortunately, many patients suffering from a lack of voluntary control over limb movements do possess a high degree of voluntary control over head movements. A food dispensing system that could be utilized by patients having control over head movements would provide a great deal of self-reliance for the many thousands of Americans who suffer from neuromuscular disorders. The NASA literature is being searched.

PROBLEM UNC-71 *Finger Joint Flexor*

An often encountered task in rehabilitation is the preservation or restoration of mobility to the various joints of the hand. Unfortunately, this task is complicated by several factors:

1. The intense pain experienced by the patient when the joint is moved.
2. A claustrophobic feeling experienced by many, especially the blind, when their hand is enclosed in a device from which they can't free themselves.
3. The skin covering the hand and fingers, as a result of the basic injury, is extremely fragile.
4. The requirements vary in each case, particular joint involved, form of the fused joint, desired motion, etc.

At the University of North Carolina Hand Rehabilitation Center, a device used to cope with this rehabilitation task consists of an inflatable section of motorcycle inner tube, a foot-operated pump, and a quick release pressure relief valve. By placing the deflated inner tube across the palm (in a position similar to that when a normal hand would grasp the tube) then inflation of the tube forces the fingers outward from the palm. Unfortunately, control of the orientation of the pressure applied to the joint is not satisfactory. However, it appears that the use of some inflatable device holds promise.

Langley Research Center personnel submitted an excellent suggestion which describes a simple system for exercising the restricted joints. A prototype has been fabricated and is being evaluated.

ORGAN ASSIST DEVICES

PROBLEM TU-38 *Portable Dialysis Unit*

Dialysis is a widely used technique for patients with kidney disease, but it has a disadvantage of requiring that the patient be attached to a bulky machine for period up to 24 hours per week. Although this lifesaving treatment is a necessity, it results in a significant handicap to the patient as well as providing less than optimum treatment. The treatment is applied three times a week and, in the intervals between the treatments, the toxic substance rises to dangerous levels in the blood stream. Thus, it would be desirable to provide a means of portable dialysis so that continuous dialysis could occur.

A computer search of the NASA document file revealed several related documents. In addition, an investigator at Lewis Research Center has been identified who appears to have technology relevant to this problem.

MENTAL HEALTH

PROBLEM IPI-3 *Eye Movement of Disturbed Children*

Retarded children are doubly handicapped by the mental deficiency and by reduced learning through normal methods. Recent studies show that a brighter prognosis is possible for some types of mental retardation through the use of special teaching techniques. These techniques are designed to bypass the blocks in the normal learning channels. This obviously means that those blocks must be identified and reasonably well understood before the learning techniques can be devised.

Reading is one of the major learning paths used by the normal individual. Retarded children often have difficulty in reading. A program is underway which is designed to study this difficulty. A system for tracking the eye using cornea reflection of a light beam is operational, but is hampered by

errors caused by head motion. Unfortunately, retarded children often are hypotense. This results in many small motions, especially head motions. Some method is needed to eliminate the head motion errors.

A computer literature search is being conducted. The NASA/Honeywell system is considered too expensive, but two other systems used by the military in helmet-mounted gunsights are being explored.

DETECTION AND TREATMENT OF HEART DISEASE

PROBLEM CP-3 *Detection and Treatment of Heart Disease*

Techniques used to extract information from pictures of Mars will be used to obtain automated information on the performance of the human heart. Medical researchers at Duke University Medical Center developed a technique to determine myocardial contractility of functional character of the cardiac muscle. This technique should be particularly useful in determining effectiveness of surgical procedures designed to improve cardiac function by improving the blood supply to the heart. The technique is thus suitable both pre- and post-operatively to determine coronary revascularization following treatment. The most appropriate surgical procedure of treatment to improve cardiac blood flow, and, in turn, cardiac function, can be determined by this technique that is based upon measurements taken from sequential coronary angiograms.

A coronary Angiogram is an X-ray image of the heart taken after injection of a radiopaque dye into the coronary artery; this procedure makes the coronary artery and the arterial bifurcations (branching points) visible. The analysis technique above relies on measurements of dimensional changes of various portions of cardiac muscle during a cardiac cycle. These linear dimensional changes can be related directly to cardiac muscle function. The measurement of these dimensional changes is accomplished by measurement of position of specific arterial bifurcations recorded in coronary angiograms. Two separate angiograms are needed, a front-back view and a side view, to determine the location in three-dimensional space of a specified bifurcation. The distance between two bifurcations is a measure of the dimension of the intervening muscle at that instant of time.

At present this procedure is implemented manually. About 20 specific bifurcation points are recorded on the two X-ray views, and the positions of these points are then recorded over several complete cardiac cycles by angiograms exposed every 1/60 second. At 60 frames per second, two projections, 20 specified bifurcations, and a total of several seconds of cineangiograms, the required determination of position changes and their time course is an exceedingly difficult and lengthy task. A reasonable method of automating this analysis of the angiograms is clearly needed if this technique of cardiac function analysis is to achieve clinical importance.

The automated reading of the 35-mm X-ray film strips should provide rapid and accurate information on the positions of specified arterial bifurcations. Accuracy should be compatible with image resolution on the order of 500 x 500 image resolution elements. It would be acceptable and probably desirable to manually identify (possibly by a light pen or similar technique) on the first film frame the specific bifurcation points to be used, and have the film reading system automatically follow the location of these points in the subsequent frames.

One approach would be to digitize each film frame and apply pattern recognition techniques. This is difficult and probably very inefficient for this problem, however, because at each frame the positions of the 20 or so desired points are already fairly well known from the analysis of the preceding frame. What is needed is a method of identifying and locating these points whose neighborhood values are already known.

The Team determined that the information of interest was at the Jet Propulsion Laboratory. Details of the JPL VICAR software program were given to the researcher and he decided that the enormity of this project required that he work directly at JPL for a short period. Thus, he applied for and received a summer fellowship at JPL for 1970. During this period, he learned the JPL image processing procedures, worked out his own algorithm, and determined that this approach could solve his problem. He then designed a modified system of image scanning and processing, which was contracted by Dicomed Corporation. This equipment has been delivered and is operational.

This significant medical problem will be solved using a modification of the JPL image processing procedures. The equipment is operational, and the actual bifurcation identification has been accomplished over about 15 frames of film. Figure B-1 shows the result of using this technique to identify a region of reduced flow (the circled area in the figure). Additional use of this technique will enable the researcher to automatically measure dimensional changes in the heart during a cardiac cycle.

PROBLEM UNC-63 ECG Processor

An ECG processor is needed to recognize a specific point of the ECG signal to be used as a gate to record ultrasonic echoes during a preselected interval of the ECG.

Ultrasonic techniques are finding increasing use in the medical field. Perhaps one of the most important uses of ultrasound in medicine has been cardiology. By making modifications to an existing ultrasonic system, the Department of Nuclear Medicine at the University of North Carolina will employ ultrasound to detect cardiac tumors, to study valve anatomy, and to diagnose pericardial infusion with more accuracy than is presently possible.

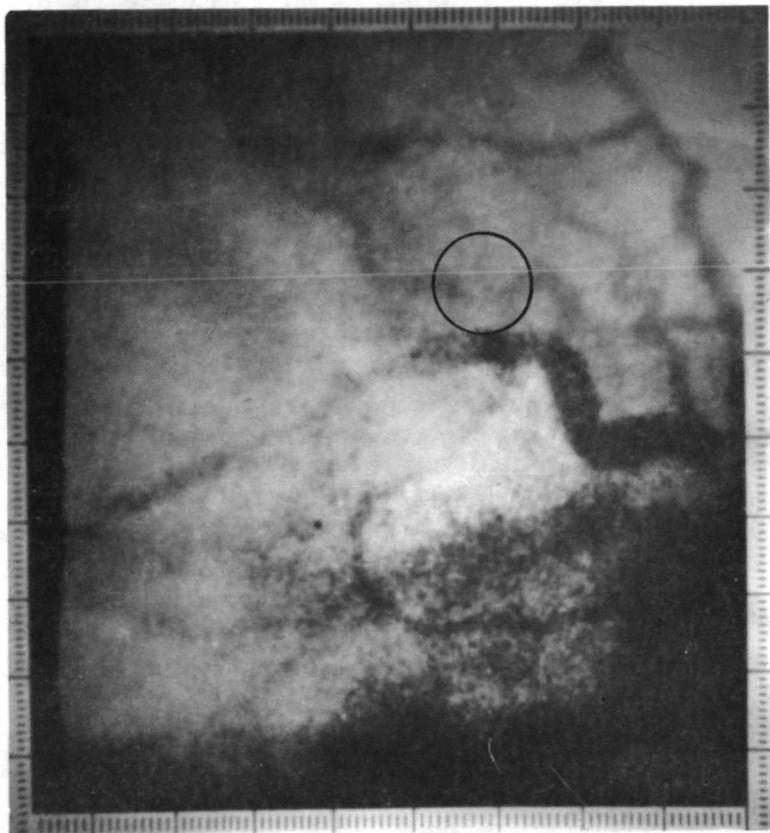


Figure B-1. X-Ray of Human Heart Enhanced by Computer Techniques.

Commercially available ultrasound systems are designed to produce echo images by displaying on a storage CRT the echoes from pulses transmitted at a constant rate. If the object being imaged moves, then the image on the CRT is blurred. Thus, the problem of imaging a moving heart is complicated. The problem originator wishes to employ a stroboscopic technique when imaging the heart by recording images during only a preselected interval of the patient's ECG. This will insure that the heart is in virtually the same position each time the echoes are recorded. Since the ECG is to be employed as a gating signal, it is necessary to process the ECG in order to recognize the beginning of each heart cycle. A processor that will recognize a specific point on the ECG signal (e.g., the peak of the R wave) is needed. The processor should be relatively immune to baseline shifts in the ECG as well as artifacts. A NASA R-wave detector is under evaluation.

PROBLEM UNC-67 *Noninvasive Technique for Detecting Implanted Artificial Heart Valve Deterioration*

Cardiac valve replacement is a well established surgical procedure. However, it is recognized that the implanted valve prosthesis is subject to a number of failure modes. Wear and deterioration, for example, produce suboptimal closing and opening characteristics thus reducing the cardiac output. Blood clots, tissue interference, and leaks around the valve mounting are other failure modes. Any of the modes can produce a catastrophic valve failure which will result in almost certain death. Valve repair or replacement can be accomplished in most instances if the condition is detected soon enough.

There are several different valve designs in use. The problem originator is primarily interested in the Lillehei-Kaster Pivoting Disc Prosthesis. In this particular design the disc movement is distinct and relatively large. It is desired to have some noninvasive technique to measure this movement, or some other parameter, which will give an indication of the initial signs of valve malfunction.

A problem statement was distributed. Several excellent suggestions have been received and are being pursued.

PROBLEM WF-88 *Accurate Determination of Arterial Pressure Pulse Transit Time*

In the arterial system, the pressure is a function of distance and time; hence, it has wave properties. The wave speed of the pressure pulse is related to the elastic modulus of the arterial wall. In addition, wave reflections that occur in the arterial system perturb the pressure function. It is known that the elastic properties of the arterial wall change in human beings with age and arterial disease. The biological problem is to detect changes in the material properties of the arterial vessel nondestructively early in the process of arterial disease. Change of the properties of the arterial wall are thought to be related to wave speed or transit time of the arterial pulse.

If the relationships between arterial wall properties and transit time or wave speed measurements of the arterial pulse could be established using improved instrumentation or improved analysis techniques, it would be an important contribution to diagnosis of arterial disease.

The primary requirement of this problem is to determine arterial pressure pulse transit time. Determination of this parameter to a precision of $\pm 5\%$ is required. As secondary requirements, it is desired to be able to obtain information about the material properties of the arterial vessel such as characteristic impedance, terminal impedance, etc.

This problem can be solved using a Pitran Pulse Detection System developed during the summer program at Goddard Space Flight Center (GSFC). The problem originator has built a duplicate of the GSFC unit and tests are underway. The unit is shown in Figure B-2.

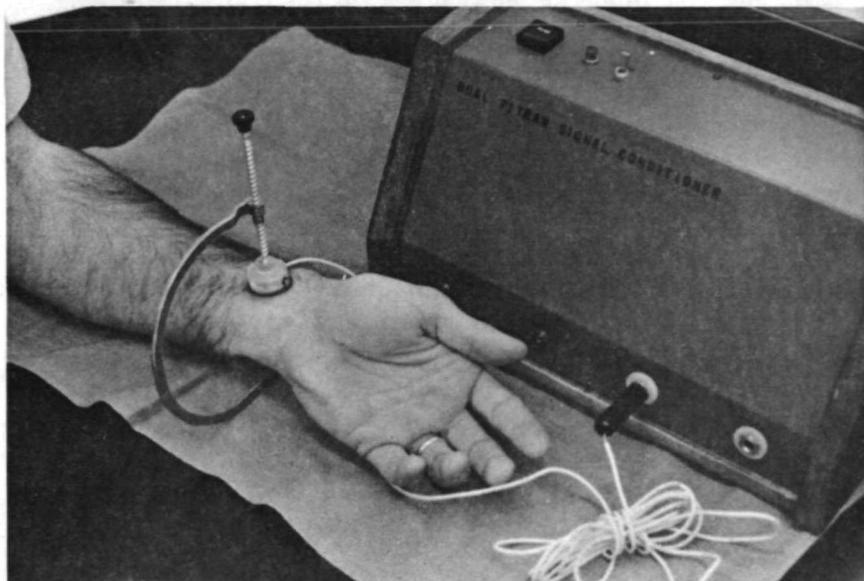


Figure B-2. NASA Pitran Pulse Detection System.

PROBLEM WF-107 *An Inexpensive Method of Monitoring Respiration in Anesthetized Primates Being Ventilated by Mechanical Respirators*

As part of a long-term study program into atherosclerosis, the Bowman Gray School of Medicine is involved in a project using primates as experimental animals. Some animals will be fed normal diets while others will be fed atherogenic diets. During these studies it will be necessary to surgically implant a number of devices for monitoring various physiological parameters. During the surgical procedures, the primate will be anesthetized and re-spired using a positive displacement animal respirator. A trachial tube inserted into the animal's throat is used to connect the animal to the respirator. It is important, of course, that the animal be properly respiration during these surgical procedures. Any interruption of the air flow supply to the animal will result in its death. These animals are specially prepared and represent a significant investment of funds and research time so that the loss of even one animal as a result of improper respiration is significant. In order to eliminate this possibility, a technique or method of monitoring the respiration of the animal is desired. A visual indication of the normal respiration of the animal is desired. For example, a meter could be used to provide a varying amplitude indication proportional to the respiration of the animal. For example, inspiration could represent a zero reading, and expiration a positive reading, so that the meter would fluctuate between zero and some positive reading during a normal inspiration/expiration cycle.

The respirator-alarm system using telemetry techniques developed at the Ames Research Center appears useful in this application. The requirements in this problem, however, are significantly simpler so that complicated telemetric equipment is not necessary. In addition, the requirements for an alarm are not necessary. The fundamental requirement is for a meter reading to indicate inspiration and expiration. It is felt that a modification of the Ames circuitry can be accomplished to provide the required monitor at a very low cost. The Biomedical Engineering Department at Bowman Gray School of Medicine is evaluating the Ames circuitry and modifying the system to this application.

DETECTION AND TREATMENT OF CANCER

PROBLEM MISC-23 *Pattern Recognition of Ultrasonograms*

Tumor detection at an early stage is a critical factor in the successful treatment of the disease. In general, the chances for cure are dramatically improved if the cancer is detected at a very early stage. Conversely, if the tumor is significantly advanced at the time of detection, little chance for cure exists. One new method being explored for tumor detection in the eye is the ultrasonogram. Basically, this consists of a scan of the eye using ultrasonic energy and a display on an oscilloscope. Although visual observation of an ultrasonogram allows one to distinguish a tumorous eye from a normal eye, a more precise method of pattern recognition is required in order to detect smaller tumors. The basic problem is to determine the subtle differences in ultrasonogram patterns of a

normal eye and a tumorous eye using some scanning process and automatic pattern recognition technique. The normal eye has a diameter of about 24 millimeters and tumors as small as 3 millimeters must be detected.

The National Aeronautics and Space Administration has broad experience in the area of pattern recognition, and it is felt that this problem is amenable to solution using advanced pattern recognition techniques. The NASA document files are now being carefully studied to determine whether applicable techniques exist. The Team also suggested a commercial instrument which may solve this problem and the investigator is investigating this possibility.

PROBLEM NCI-9 Improved Emulsion for Autoradiography

Knowledge of photographic emulsions by a NASA researcher may improve the emulsions used in the autoradiographic study of cancer.

The study of cancer in experimental animals can be facilitated by labeling the cells with radioactive tritium. The tritium attaches itself to the DNA molecule, and the division of the tumor cell produces new labeled cells. A process called autoradiography detects a radioactive cell by placing a film of photographic emulsion over the cell and exposing the emulsion by the radioactivity. Existing emulsions require an exposure time on the order of months. If a much faster film can be developed, then this technique can be used clinically in following the progress of human cancers. This will provide a valuable new technique in the fight against human cancer.

A computer search of the literature on nuclear emulsions revealed that scientists at Goddard Space Flight Center had employed sounding rockets carrying nuclear emulsions to study the composition and energy spectra of low energy cosmic rays. The TUO at GSFC was presented with this problem and he suggested that the Team contact Dr. Jacob Trombka who is quite knowledgeable in this field. Dr. Trombka has experimented with several types of specifically prepared noncommercially available emulsions that will reduce the required exposure time. A Team member met with Dr. Trombka and he discussed these techniques at length. The National Cancer Institute subsequently contracted with a research team at Duke University to undertake a study to develop improved emulsions. Dr. Trombka has been in frequent contact with the Duke team and his ideas will be implemented and evaluated.

PROBLEM NCI-10 Scanning Tumors in Small Animals with Gallium-67

An analytic technique developed for aerospace radiation detection is being considered for scanning tumors in animals.

Gallium-67, a radioactive isotope, possesses the special property of concentrating in various types of tumors when administered orally or intravenously to a patient. The mechanism of gallium uptake is not

well understood; it is not known whether there is a direct binding of gallium in the tumor tissue or binding to some other agent that, in turn, is concentrated by the tumor. Whichever is the case, Gallium-67 appears mainly in viable rather than necrotic tumors. In addition, studies indicate that Gallium-67 is superior to other commonly employed tumor-scanning agents in absolute tumor concentration and in ratio of tumor to normal tissue concentration. These observations are possibly the most significant recent developments in nuclear medicine.

By administering Gallium-67 to a patient and scanning the body with an instrument that will detect the presence of radioactive substances, the location as well as the size of a tumor can be determined. Radiologists currently employ a variety of camera and scanning systems that are useful in locating tumors in human beings but are relatively ineffective in studying the response of the tumor to therapy. In order to follow tumor growth on a day-to-day basis, a high resolution scanning system that is sensitive to Gallium-67 is needed. In particular, the scanning system should be suitable for scanning the entire bodies of small experimental animals. Such a system would offer a unique opportunity to study methods of inhibiting or retarding tumor growth.

A solution to this problem has been suggested by a NASA contractor, Ball Brothers Research Corporation, utilizing technology developed for the space program. The National Cancer Institute is considering a proposal to implement the proposed solution.

PROBLEM NCI-12 *New or Improved Methods of Detecting Breast Cancer*

Breast cancer is common: 5-6 percent of all women will at some time in their lives develop breast cancer. If cancers are discovered when they are still localized, the majority of them can be cured by surgery and radiotherapy. Provisions for earlier and more comprehensive treatment of patients with breast cancer require improved techniques for detecting malignant tissue during the initial stages of growth. Four techniques for detecting breast cancer are in use at present: physical examination, thermography, xerography, and mammography.

None of these techniques is sufficiently reliable. A combination of these methods provides an improved probability of detecting breast cancer; however, none of the methods provides conclusive results. Each of the methods has shortcomings. New or improved methods, techniques, or approaches for detecting breast cancer at an early stage are needed.

A problem statement was circulated to the NASA field centers and the Team received two suggestions that warranted additional investigation: (1) the use of liquid crystal thermography to obtain visualization of the temperature patterns of the breast with minimum effort and cost, and (2) vibrational methods for detecting tumors deep under the skin surface.

These suggestions were evaluated by a member of the National Cancer Institute's Detection and Diagnosis Subcommittee. While there was some merit in both suggestions, there was no reason to believe that these techniques would offer an improvement over methods presently in use. The Team plans to assist on specific problems encountered in improving existing breast cancer detection techniques.

PROBLEM TU-22 X-Ray Microplanigraph

An aerospace method used for analysis of printed circuit boards is being applied to obtain improved X-ray techniques of cancer detection.

Cancer is the second largest cause of death in this country and, according to a recent survey, is the disease most feared by the American people. The state of cancer treatment today is such that generally those cancers that are found early can be successfully treated. The easiest cancers to detect are those that are on the surface of the body, and those most difficult to detect are those deep within the body. Thus, cancers arising deep within the body usually result in the death of the patient because detection of the cancer occurs too late.

It is desirable to develop an instrument capable of detecting tumors deep within the body. In addition, it is desirable to be able to determine whether or not the tumor is malignant or benign and the extent to which the tumor has spread. One common method of detecting tumors is by X-ray. Unfortunately, when the entire body is X-rayed, small tumors cannot be detected because the background level of signal of the X-ray is vastly increased by the thickness of the body. It would be highly desirable to develop a technique whereby X-rays could be made of lamina regions only. If X-rays could be made of thin laminae, smaller tumors could be detected. The basic problem then is to develop a method whereby X-rays of thin laminae can be made of a patient instead of the conventional X-ray technique.

The technique of making X-rays of thin laminae with high resolution is called X-ray microplanigraphy. This technique has been theoretically possible for many years. Recently, a development in NASA has significantly increased the possibility of developing such a technique. NASA developed such a technique for inspecting multilayer printed circuit boards layer by layer with a resolution of 0.001 inch. This technique has been well developed by a NASA contractor at Illinois Institute of Technology. Basically, it involves moving the X-ray source and detector in a particular geometrical arrangement in such a manner that only thin laminae are measured. The work was funded by MSFC, and the Team was apprised of the work through a computer search. The Team then contacted MSFC for additional information and was referred to the IIT investigator. The problem originator has discussed this technique in detail with the NASA contractor and has decided that this work is highly relevant to his investigation. An example of the use of the technique is shown in Figure B-3.

The device has been implemented at the Tulane School of Medicine. The researcher indicates that tests to date have shown that it is possible to distinguish malignant from benign lesions in the breast. This will eliminate the need for much surgery in cases of suspected breast cancer. The National Cancer Institute is now evaluating a proposal to launch a major study using this approach.

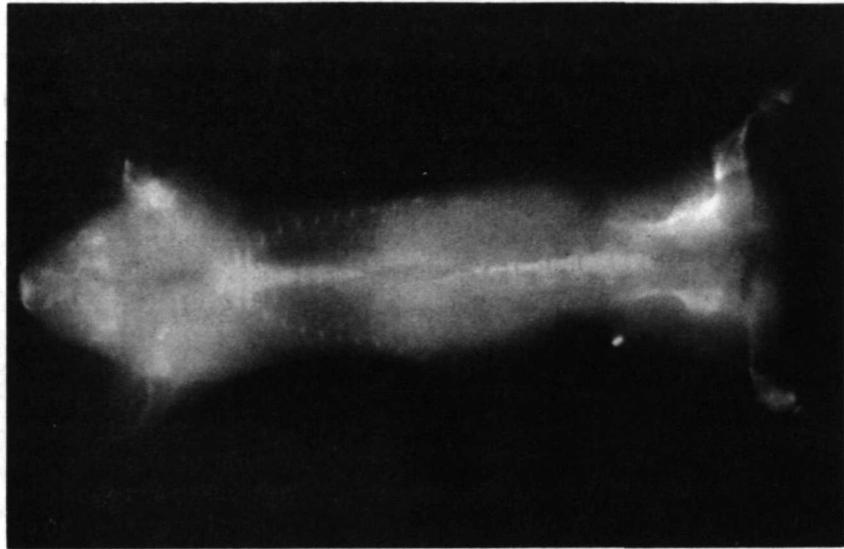


Figure B-3. X-ray Microplanigraph of a Mouse.

PROBLEM UNC-75 Improved Antigen Assay Sensitivity

Successful cancer treatment often depends heavily on early detection. Thus, where feasible, mass screening methods such as the "Pap Smear" can be very effective. The problem originator is developing such a technique to detect several different cancers.

In this technique, small quantities, a few tenths of a milliliter, of blood serum are analyzed using a Technicon AutoAnalyzer. During the analysis the offending antigen combines with a specific antibody to form a much larger molecule. The presence of the larger molecule is detected using a nephelometer which measures the light reflected at 90°. Because of base line drift and the very minute quantity of antigen present, the current measurement is unreliable.

A method is needed that permits accurately detecting particles 500 to 3000 angstroms in diameter suspended in serum in concentrations of 5 $\mu\text{G}/100 \text{ ml}$.

The miniature AutoAnalyzer, a joint development of NASA and the Atomic Energy Commission, is being investigated for application to this problem.

PROBLEM WF-115 A Means of Detecting the Onset of Shock

This problem has a companion one to problem NCI-3, Automated Blood Pressure Measurement of Critically Ill Patients, which is discussed in Section 3 of

this report. In both problems the solution is some measure of the onset of shock which will allow corrective action to be taken early enough to prevent the development of irreversible shock which results in death. One method of solving this problem appears to be the use of the NASA oximeter which was developed at Ames Research Center. Initial tests on the use of this device were conducted at the National Cancer Institute and by the problem originator at the Bowman Gray School of Medicine. An application engineering request has been submitted to NASA Headquarters for the development of a second generation model of this device.

ECOLOGY

PROBLEM MISC-32 *Selective Permeable Membranes*

The Environmental Protection Agency currently has a need for miniature air pollution sensors to be used in field monitoring. One concept being investigated involves the use of permeable membranes through which a particular air pollutant would diffuse into a fuel cell chamber. The addition of the air pollutant would cause a change in the electrical characteristics of the fuel cell which would in turn be used as an indicator of the level of the particular air pollutant. A key factor in the success of this approach is the availability of membranes that are permeable for particular air pollutants. A search of the NASA literature is now underway to determine whether membranes developed in aerospace research are applicable to this problem.

PROBLEM TU-9 *Human Voice Analysis*

An aerospace technique for improving speech transmission from aircraft is being applied in analyzing speech defects.

Approximately 6-7 percent of the population is considered to have either temporary or chronic speech defects. In chronic cases, inadequate understanding of the causes of speech defects hampers treatment. For example, one speech defect is characterized by a pitch that is either too high or too low and can be caused by contact ulcers, polyps, polypoid degeneration, or chronic laryngitis.

A technological impediment exists in the analysis of speech defects because of the inability to precisely quantize characteristics of the human voice. This is further complicated by the fact that many changes in the human voice are easily detected by the ear but are often quite subtle in their spectral density or frequency changes. A number of techniques have been employed in an attempt to quantize the human voice, but to date no technique has been found that permits the therapist to measure changes in the human voice before and after therapy.

Speech consists of a broad fundamental frequency and many harmonics. Small shifts in fundamental frequency and amplitude cause large changes in the human voice. Frequency spectrum analyses must be able to detect

fundamental frequencies that range from as low as 50 Hz for low-pitched male voices to more than 400 Hz for high-pitched children's voices. The technique must measure fundamental frequencies to a precision of 1 Hz and amplitude to a precision of 1 dB. The analysis technique must take into account both fundamental frequency and harmonics and their relation to the fundamental frequency. Although not required, real-time analysis is desirable.

Spectral analysis techniques developed by the NASA Michoud Assembly Facility is applicable to this problem. The problem originator discussed the applicability of these techniques with the cognizant NASA personnel and the NASA personnel agreed to process clinical data collected by the problem originator. Data collection is underway.

REMOTE HEALTH CARE SERVICES

PROBLEM UNC-74 *Remote Health Clinic Communication System*

A statewide system of health care delivery to remote areas is being established. According to this plan the state is divided into several geographical areas. Within each area a major hospital is designated as that area's center. Outlying from each center are small clinics located in remote areas. Each clinic's diagnostic capability is organized around the trained skills of a nurse practitioner. A nurse practitioner is defined as a registered nurse with additional training. Medical backup is provided by the center's staff. Currently, this backup consists of telephone (voice only) and automotive (move either patient or doctor). Some method is needed to rapidly and economically transmit vital signs, ECG, voice, and possibly visual information.

A complicating factor is the inadequate telephone service. In most cases small, local telephone companies provide the service thus requiring crossing several exchanges to cover short distances. In addition, the equipment, including the telephone lines, is old and in need of replacement.

The NASA IMBLMS Program along with several medical communications studies conducted by Johnson Space Center are being investigated.

KIDNEY DISEASE DETECTION AND TREATMENT

PROBLEM WF-112 *Method of Correlating Composition with Differences in Surface Morphology of Kidney Stones*

This problem is related to and, indeed, has been identified as a result of previous work on biomedical problem WF-98, "An Improved Technique to Yield Precise Information on Surface Morphology of Kidney Stones." Under this previous biomedical problem, a number of kidney stones were analyzed

by means of scanning electron microscopy at the NASA Marshall Space Flight Center. In this study it was desired to identify the micromorphology of kidney stones of various types and to attempt to correlate the morphologic characteristics of kidney stones with various crystalline types. It was specifically desired to determine whether or not surface morphology is a factor in kidney stone formation.

Information obtained as a result of the cooperation of NASA personnel at the Marshall Space Flight Center is providing for Dr. W. A. Boyce a number of scanning electron micrographs of various characteristic kidney stone types has been extremely useful in Dr. Boyce's studies. The scanning electron microscope studies, however, indicated that there are certain lamellar characteristics on the kidney stone surfaces observed. These surface characteristics showed up in many of the scanning electron micrographs as striations on the surface. In order to probe further into the mysteries of kidney stone formation, Dr. Boyce has considered it extremely important to determine whether or not these striations or lamellar-appearing variations on the scanning electron micrographs are related to compositional changes of the kidney stone itself. Consequently, Dr. Boyce wishes to compare certain kidney stones using scanning electron micrographic techniques on the same kidney stones to determine, using the best available techniques, the microcomposition of the kidney stone surface. Essentially, a method of obtaining the microcomposition (the composition of portions of the kidney stone surface 1 or 2 micrometers in diameter) of kidney stones is desired to permit comparison of the surface morphology with composition. The possession of this information will provide an answer to the question of whether the lamellar-like structures, shown on many of the kidney stones, are actually associated with compositional differences in the kidney stones.

The scanning electron microscope laboratory at the NASA Marshall Space Flight Center is being fitted with an electron microprobe. This unit will permit measurement of certain elements of the kidney stones. Measurements of composition of areas down to 1-2 micrometers in diameter can be made. Sampling of such small areas of the stone's surface will permit correlation of compositional data with morphologic data as obtained with the scanning electron microscope. A request has been made to Mr. Juan Pizarro, Technology Utilization Office, Marshall Space Flight Center, for assistance on this problem with positive results. Dr. Boyce is presently preparing the kidney stones for processing at Marshall Space Flight Center.

REDUCTION OF INFANT MORTALITY

PROBLEM IPI-1 Beat-to-Beat Heart Rate Monitor

The study of a developing infant, or a mentally retarded child, is complicated by the difficulty of determining the reaction to a stimulus. Heart rate is a sensitive indicator of a stimulus such as light or sound, but the response is

required on a beat-to-beat basis. While several methods are available for measuring heart rate, care must be taken that the measuring technique is minimally traumatic to the patient; otherwise the response is either complicated or even eliminated by the traumatic effects of the measuring system.

The problem originator obtains the heart rate from the ECG which is recorded on magnetic tape and analyzed by computer at some later time. Unfortunately, motion artifacts, muscle noise, 60 Hz interference, shifting base lines, and variations in R-wave amplitudes all make the computer identification of the individual R waves extremely difficult. As a result of this process, there is a several day delay before test results are made available to the clinician. This delay is unacceptable. Some way of simplifying the computer processing or some real time method is needed.

Information on the R-wave detector (with automatic sensitivity control) and several computer programs have been sent to the problem originator. Information on a commercially available cardiotachometer that uses the R-wave detector circuitry has also been furnished to the problem originator.

PROBLEM TU-39 *Respirator Neck Seal*

Many infants experience respiratory distress and a variety of techniques are presently being explored to provide the necessary assistance during the critical period early in life. One method is to provide a positive oxygen pressure to the upper airways. The medical investigator has built a unit that provides this therapy, but he is experiencing difficulty with the neck seal. He is interested in a method of improving the seal for this existing respirator. The seal must provide closure for up to 12 centimeters of water pressure for a 70 percent oxygen environment. A critical factor is the ability of the seal to prevent chaffing or undue constraint for the infant's neck.

The Team is presently investigating a number of sealing devices within the NASA community that may be applicable to this problem.

RESPIRATORY DISEASE DETECTION AND TREATMENT

PROBLEM UNC-70 *Tantalum Suspension Creation and Delivery System*

The respiratory system is composed primarily of soft tissue. Resolution of X-rays of this type of tissue is poor. As a result of the usefulness of X-rays in respiratory disease detection is limited.

Several techniques are being explored as possible methods of circumventing this problem. One method makes use of a fine powder composed of tantalum particles (particles are 5 to 10 micrometers in diameter). The patient breaths

an atmosphere containing a reasonably uniform suspension of these particles. Depending on particle diameter, certain sections of the respiratory airways are coated with tantalum dust. The coated tissue is thus made more X-ray opaque, increasing X-ray resolution.

A satisfactory technique for creating and delivering this uniform suspension to the patient has not been worked out. The problem originator mixes the tantalum powder in water, using a wetting agent, then atomizes this slurry with a Bird Space Technology's micronebulizer. The difficulty experienced with this method is that the particles tend to stick together forming clumps. The resulting tissue coating is not uniform and X-rays are spotty.

Currently, several suggestions from Langley Research Center are being investigated. They appear very promising.

PROBLEM UNC-72 Retractable Cover for Specimen Catheter

Effective treatment of respiratory infections often requires an accurate identification of the involved organisms. To obtain this identification, a specimen from the infected area is obtained by introducing a specimen catheter through the mouth and throat into the trachea. Unfortunately, organisms present in the mouth and throat can easily be picked up by the catheter as the catheter is passed through these areas. This very likely results in an erroneous typing of the organisms in the trachea.

Some method is needed that would cover the catheter during insertion. Once the catheter is in place, the cover would be retracted. During this uncovering process, organisms attached to the cover must not be allowed to contaminate the specimen catheter.

The catheter's outside diameter is 3-4 mm, and its length is 18-20 inches. Any material used must be nonirritating to the tissue of the mouth, throat, and trachea.

Langley Research Center personnel submitted two suggested solutions. Both are being evaluated.

IMPROVED SURGICAL PROCEDURES

PROBLEM MISC-25 Micro-Connector for Magnetically Guided Catheter

Researchers at Massachusetts General Hospital are developing a system to aid in guiding a catheter to various locations in the cardiovascular system. This system is expected to provide a nonsurgical means of correcting certain cardiovascular disorders that are now correctable only through surgery. One

of the procedures that is now being employed in experimental animals requires that a latex balloon be inflated and deposited in an artery. The balloon is guided to the proper location and then inflated by the injection of serum albumin through the catheter. Should the patient show untoward effects or the balloon be found to be improperly positioned, the balloon must be quickly deflated and withdrawn. If the balloon is positioned properly, the ferromagnetic catheter tip is heated by an external R.F. field which causes localized hardening of the serum albumin thus sealing the balloon. The catheter is then withdrawn leaving the balloon in the artery. The balloon simply slips off of the tip of the silicon catheter. It is felt that heating the ferromagnetic tip could be done simpler and less costly by providing a small heating element inside the tip. In this case it appears necessary to employ a miniature electrical connector which disconnects when the catheter is withdrawn. Technological assistance is needed in designing and fabricating such a device. This idea is suggested only as a possible approach; alternate approaches to sealing and detaching the balloon should be considered.

The solution to the problem of sealing and detaching the balloon should satisfy the following requirements:

- 1) The technique should permit the balloon to be pretested and must permit the balloon to be deflated if it is improperly positioned.
- 2) Sealing and detaching must be done without allowing any substance in the catheter that would be harmful if spilled into the blood stream.

An engineer at Langley Research Center has suggested an approach to the problem which is presently under evaluation.

DETECTION AND TREATMENT OF DENTAL AND ORAL DISORDERS

PROBLEM VAM-17 *Automated Stereo Photographic Mapping*

One in every 600 to 700 children is born with a cleft of the lip and/or palate. Extensive experience at correcting this deformity and its related dental and speech problem indicates that with the proper attention the cleft lip and palate child can be expected to be no different from other children. The face of the infant begins to develop at approximately 7 to 9 weeks after conception. The lip develops about the seventh week and the roof of the mouth, which is the hard and soft palate, at approximately 9 weeks of life. The lip and palate develop independently. It is therefore possible to have either a cleft of the lip or a cleft of the palate separately or together. The degree of the cleft can vary from a slight notching of the red portion of the lip to the complete separation of the lip. The portion of the bone where the teeth grow through the gums may also be involved. The lip can be cleft

to any degree on one or both sides. The hard and soft palate may also vary in degree from a slight notching of the end of the soft palate to a complete separation through the roof of the mouth. Any combination of lip and palate clefts may exist. Most investigators feel that there is sometimes a hereditary factor in the formation of cleft palate. Research has also demonstrated that nonhereditary factors including nutritional deficiencies, infection, and various drugs may cause similar defects. An infant with a cleft of the lip and/or palate has the potential for growing and developing normally. The cleft is not due to something missing; rather it is due to something that has not joined together during the early development. Although a wide cleft of the lip and palate may be present at birth, the two separate portions of the palate can still grow and develop normally. The lip is often repaired first, usually during the first month or when a child reaches a certain weight. The soft palate can be repaired at the same time as the lip although many surgeons prefer to do it later. Timing for closure of the hard palate cleft varies greatly. Often the surgeon must wait until the bones in the palate adjacent to the cleft grow and increase in size before the hole can be closed. In some instances the hard palate cleft will not be closed until 5 years of age. The proper timing for hard palate closure will be determined after consultation with the orthodontist and a careful study made of the palate size and form. There is no such thing as the only way to surgically close the cleft of the lip and/or palate nor will the children with the same defect be operated on at the same age. Every face even with the same type of cleft will grow differently. It is the important factors of when and how the face changes that influence the surgical decisions. In order to assess the changes that take place in the palate and the lip as a result of growth and/or corrective procedures, it is common to make a series of plaster casts of the child's palate and lip. Important quantitative information concerning the nature of the deformity has been obtained by the problem originator through stereophotogrammetric techniques which have been employed to produce a contour plot of the plaster casts. A contour plot presents the surgeon with a more accurate description of the deformity and permits a more complete corrective procedure. Stereophotogrammetric techniques for contouring the plaster casts yield high quality results; however, since the method has not been automated, it is too time consuming and too costly to be applied to all but a few cases.

The problem has been discussed with Langley Research Center personnel. One technique suggested by LRC personnel, the use of Morie Interference Patterns, is being pursued.

BASIC MEDICAL RESEARCH PROBLEMS

PROBLEM IPI-4 *Detection of Guppy Embryo Motion*

Frog and guppy embryos are excellent subjects for laboratory studies. By observing the initial motions made by the embryos in both natural mediums and modified mediums, a great deal can be learned about the neuron and synaptic development sequence.

The problem originator is using such a procedure. He monitors the spinal cord activity through strategically located microelectrodes and attempts to correlate the initial embryonic movements with the spinal cord activity. Unfortunately, the motion monitoring, which may last for 24 hours, must be done visually. An automatic monitoring system is required which will quantify.

The embryos are approximately 6 to 8 mm in length and 1 mm in width. They are suspended motionless in a water medium, or possibly a saline solution, to simulate their normal environment. Chemicals such as strychnine may be added to this medium to selectively block inhibitory synaptic junctions. The medium and the embryo are usually contained in a petri dish. The particular motions of interest are various motions of the embryo's tail. Very little lateral or fore and aft motion of the embryo results. In addition, the microelectrode basically fixes the overall position of the embryo.

One group attempting to monitor this tail motion places a very fine wire next to the tail of the embryo and detects artifacts when the embryo moves its tail. This method has several drawbacks. First, the embryo may impale itself on this fine wire. Second, the embryo may have a very small lateral motion and move away from the wire and thus interrupt any output. Another method suspends the medium and the embryo from some type of phonograph cartridge. Any motion within the medium is sensed by the cartridge. This would appear to be some variation of the micrometeroid detector developed by Ames. One major problem suspected, but not verified, is that the water motion resulting from the embryo's motion would prevent detecting ensuring embryo movements.

A literature search has been initiated and the Doppler ultrasound device from Ames is being investigated as a possible solution.

PROBLEM MS-4 *Detection of Obesity*

Obesity in adults results in a reduced life expectancy from several diseases such as heart disease and diabetes. If a child is obese at age 5, he will probably have problems with obesity for the rest of his life. In order to correct this problem, it is desirable to detect the onset of the problem in young children. Being overweight does not imply obesity so that a simple measure of weight is not adequate. A measure of total body fat or body density is required. In addition, this method should be easily adaptable for clinical use with children.

A computer search of the NASA document file revealed several documents of interest which are now being evaluated by the problem originator.

PROBLEM MS-7 Energy Expenditure Measurement

A medical research team from the United States is presently studying the cultural and medical practices of a tribe in a remote region of the Amazon Jungle. This tribe consumes very little food and has a remarkable cultural practice of a morning regurgitation exercise which is brought on by chewing a particular vegetable substance. The medical question of interest concerns their energy expenditure in relationship to dietary intake which is quite small. The medical team desires to determine how this energy expenditure can be maintained for a relatively low dietary intake.

A method of measuring energy expenditure over 24 hours is required. This method must require only minimum instrumentation because of the hostile environment for electronic equipment and because of the difficulty of transporting heavy equipment into a remote region. An information search has been forwarded to the investigator and in addition, the Team contacted personnel at Johnson Space Center (JSC) to discuss energy expenditure measurements. A novel technique developed at JSC has been forwarded to the problem originator for evaluation.

PROBLEM TU-10 Quantization of Heart Tissue Hardness

Techniques developed to study aerospace materials have been used to study the human heart during pathological examination.

Examination of the various organs of the human body following death can reveal not only the cause of death, but other conditions affecting the person at the time of death. Research at the Tulane University School of Medicine has shown that a peculiar softening of the heart tissue can be seen in some patients that did not die of heart disease. The cause of this unusual softening is not known, but a number of factors are believed to be important. For example, there appears to be an infarction and a definite softness in the heart tissue. The reasons for this are being sought in experimental work using rats in which the blood is cut off temporarily from portions of the heart in order to discover the changes in the heart tissue. Simultaneously, studies are being conducted on human hearts in autopsy examinations to determine whether this soft region can be attributed to any known condition of the human being prior to death. In order to carefully characterize these soft regions, a means of measuring softness of the heart tissue is required. The researcher has attempted to use a conventional eye tonometer for this purpose but the results have not been reproducible.

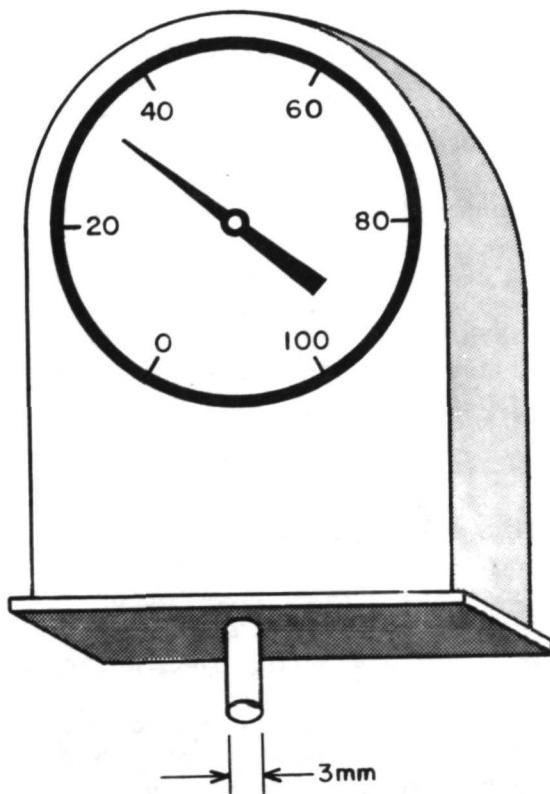


Figure B-4. Hardness Tester.

PROBLEM TU-35 *Subcutaneous Temperature and Power Density Measurement in a Microwave Field*

The widespread use of microwave generating equipment in this country has created a significant level of microwave exposure for the general population. The accepted safe limit for microwave exposure in this country is taken as 10 milliwatts per square centimeter, but it is interesting that the accepted safe exposure limit in the Soviet Union is now 0.1 milliwatt per square centimeter. For this and other reasons, considerable research is underway to determine the adequacy of the United States limit. Part of the difficulty in determining the microwave effects on the biological system is caused by the difficulty of making measurements in experimental animals exposed to a microwave field. It is likely that the introduction of an animal into an existing field would disturb the field and in addition the measurement of temperature in an animal is complicated by the fact that the microwave radiation may produce a different heating effect in the temperature sensor than in the experimental animal. A means of making a subcutaneous temperature and power density measurement in a microwave field is required that eliminates the above problems.

An information search has been conducted and a problem statement has been circulated. The problem originator is now evaluating the initial responses from the problem statement circulation. One suggestion from the Skylab prime contractor on sea state measurement appears applicable.

PROBLEM UNC-76 *Blood Pressure in a Rat's Tail*

Rats are often used in laboratory experiments, and the taking of their blood pressure is a common procedure. In those cases where the rat's blood pressure must be checked several times a day over a period of weeks, the problem is complicated. The method for measuring the pressure must cause little or no injury to the rat. The rat's tail appears to be the most convenient place to make this measurement. As a result, several methods currently exist, but each has a shortcoming.

One method is very similar to the cuff method for taking human blood pressure. The rat is placed in a special holder with his tail sticking out. The cuff consists of a metal ring with a inflatable diaphram mounted inside. A small microphone is used to pick up the sound identified with systolic pressure. Unfortunately, the system does not provide diastolic pressure. Another method is a form of plethysmography where volume changes in the rat's tail are correlated to blood pressure. The latter method may be unreliable.

Some method is needed that causes no injury to the rat, is easy to use, and provides a reliable pressure measurement. Possibly some improvement of the cuff concept is the answer. Currently, computer searches of pressure measuring techniques are being reviewed.

PROBLEM VAM-12 *Heart Rate Tachometer*

A heart rate measuring device developed for the Skylab program may have uses in clinical medicine. The problem originator is concerned with the problem of assessing the extent of the loss of mental function by persons having experienced brain damage. Patients having suffered brain damage (e.g., a stroke victim) will be subjected to tests in which they are given information at varying rates and are expected to make simple decisions. For example, the patient may be shown a movie of a series of automobiles passing a certain point and will be required to press a button each time a particular sequence of cars is encountered (e.g., two red cars immediately followed by one blue car). The frame speed of the movie will be increased until the patient experiences difficulty in making decisions. The problem is to find a quantitative measure of the level of difficulty that is experienced by the patient. The error rate is, of course, important but provides insufficient information to adequately determine the point at which decisionmaking becomes particularly stressful. One of the parameters that will provide additional information is heart rate. Heart rate will provide an indication of mental stress and should be responsive to subtle changes in levels of stress. While heart rate can be determined by a number of methods, it is necessary to have a noninvasive technique that will not arouse the awareness of the patient. This research should lead to a clinical method that will be useful in determining the extent of impaired mental function.

A heart rate tachometer that was developed as a possible candidate for monitoring the astronauts' heart rates during the Skylab mission has provided a potential solution to this problem. The proposed system, which was suggested by a Marshall Space Flight Center employee, consists of an ear plethysmograph together with associated tachometer circuitry. The plethysmograph employs a light source that transmits light energy through the ear to a photocell. As the heart beats, the quantity of blood in the ear changes, thus modulating the intensity of the light energy received at the photocell. The tachometer circuitry averages over several heart cycles and produces a voltage output that is proportional to the heart rate in beats per minute. A digital or analog voltmeter is then used for displaying the heart rate. The expected accuracy of the system is ± 1 beat per minute.

The MSFC Technology Utilization Office has arranged for a unit (shown in Figure B-5) to be lent to the problem originator.

PROBLEM WF-117 *Blood Flow Measurement Via Thermal Dilution*

Measurements of blood pressure and flow rate in various parts of the body are necessary to determine the adequacy of perfusion and to study, detect, and monitor disorders of the heart, lungs, kidneys, and vascular system. It appears that current medical practice concerning the circulatory system is blood-pressure oriented rather than blood-flow oriented because blood pressure is easier to measure. Blood flow, however, is a more direct measure of the adequacy of tissue perfusion and the exchange of nutriments and wastes. The problem originator wishes to develop a system for *in vivo* measurements of blood-flow in small vessels. Although a number of blood flow techniques have been developed, the *in vivo* measurement of blood flow in small vessels remains a difficult problem. One flow measurement technique is that of thermal dilution. By heating flowing blood *in vivo* and making multiple temperature measurements downstream, it is possible to compute blood flow rate from the differential temperature measurements. Thermal dilution techniques, although commonly used, are of particular interest since recent developments in miniaturizing heating elements and temperature sensors might make possible the development of an extremely small flow sensing probe for *in vivo* use.

The probe should be no larger than a 22-gage needle. Blood temperature should be measured to 0.1°C . The system response time should be less than 100 milliseconds.

OTHER, MISCELLANEOUS

PROBLEM EU-12 *A Rapid Method of Applying EEG Electrodes*

A special helmet developed by NASA may prove useful in measuring neurological disorders.

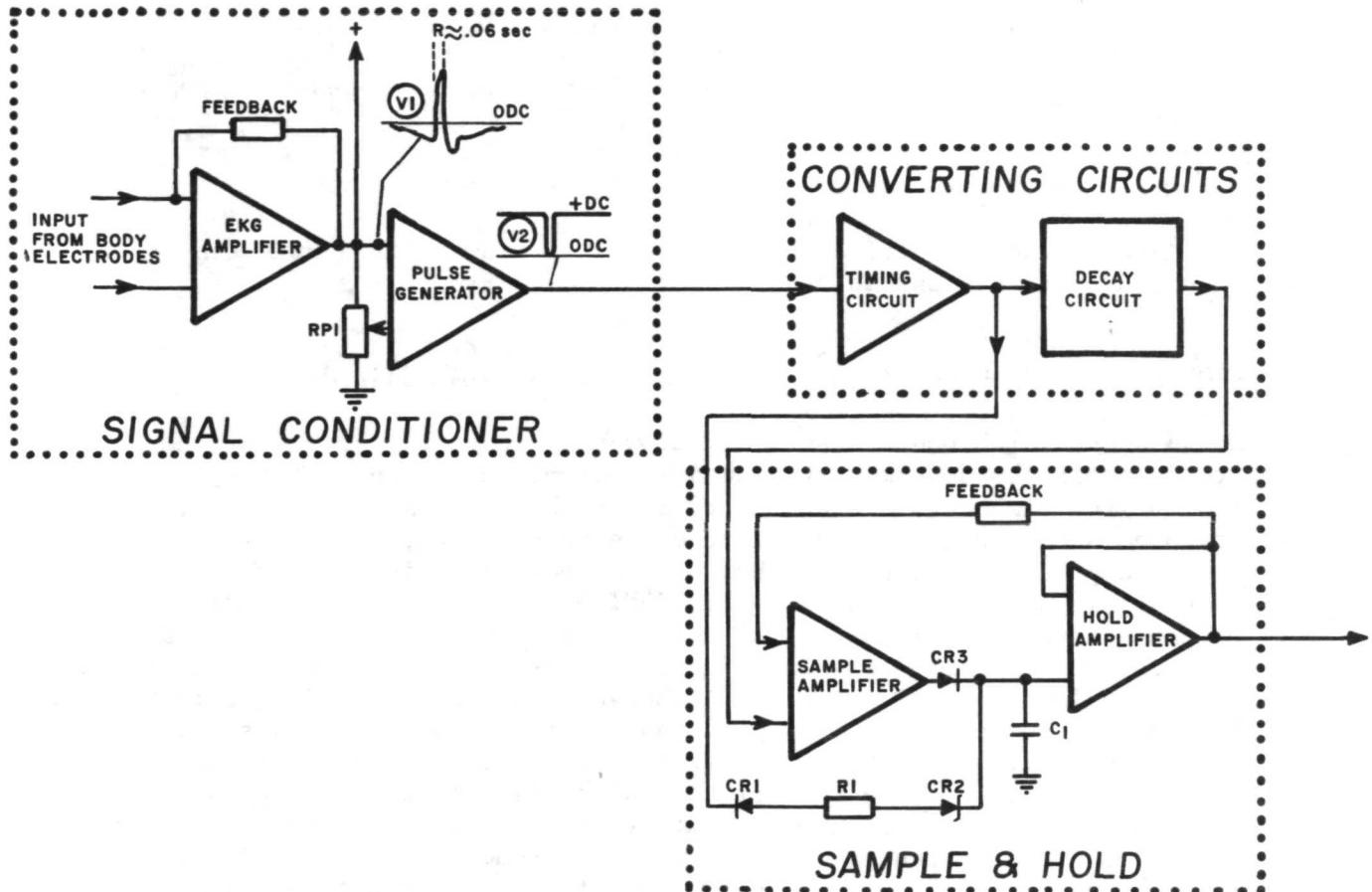


Figure B-5. NASA Cardiotachometer.

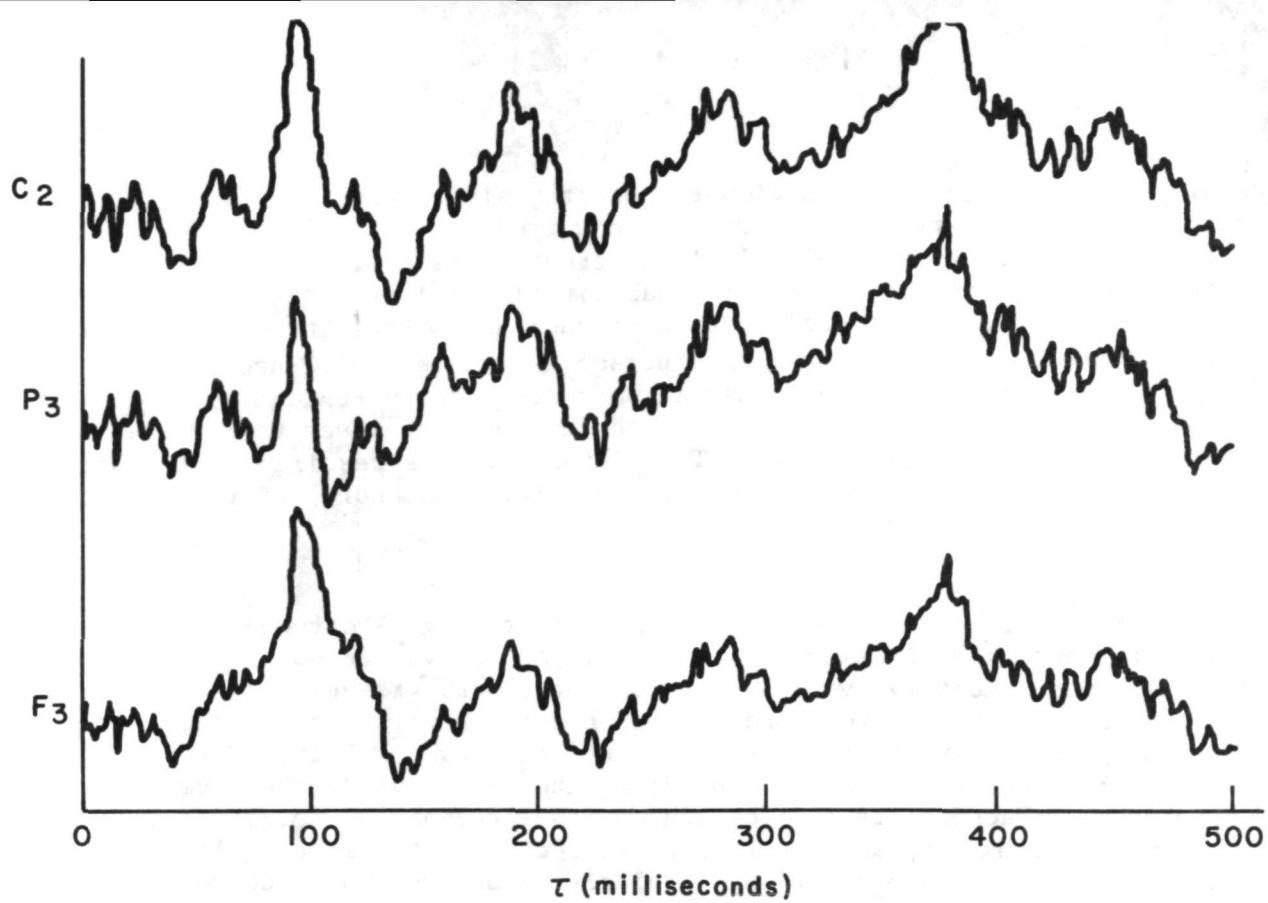
People with neurologic dysfunction represent a significant portion of the patients undergoing rehabilitation in the United States. Neurologic dysfunction can occur as a result of birth defects, disease, or traumatic injury. Emory University Regional Rehabilitation Research and Training Center is active in the rehabilitation of such patients. One of the first things to be determined about such a person is the degree of neurologic dysfunction. One program objective at Emory University Regional Rehabilitation Research and Training Center is to develop techniques to measure the degree of neurologic dysfunction. This information is required at the beginning of treatment because, if the patient cannot process sensory information, there is little hope for rehabilitation.

At the present time, evoked responses as measured by electroencephalograms (EEG) are used as an index of dysfunction. In this technique, stimuli of various kinds (auditory, visual, tactile, etc.) are presented to the patient, and the EEG is recorded from electrodes attached to the patient's skull at points appropriate to the type of stimulus. Multiple electrodes are required, varying from 3 to 16, depending on the various circumstances. Attachment of these electrodes by conventional techniques (e.g., collodion) is very time consuming and frustrating to the patient. It can also be quite alarming to the patient, particularly to one who has received shock therapy.

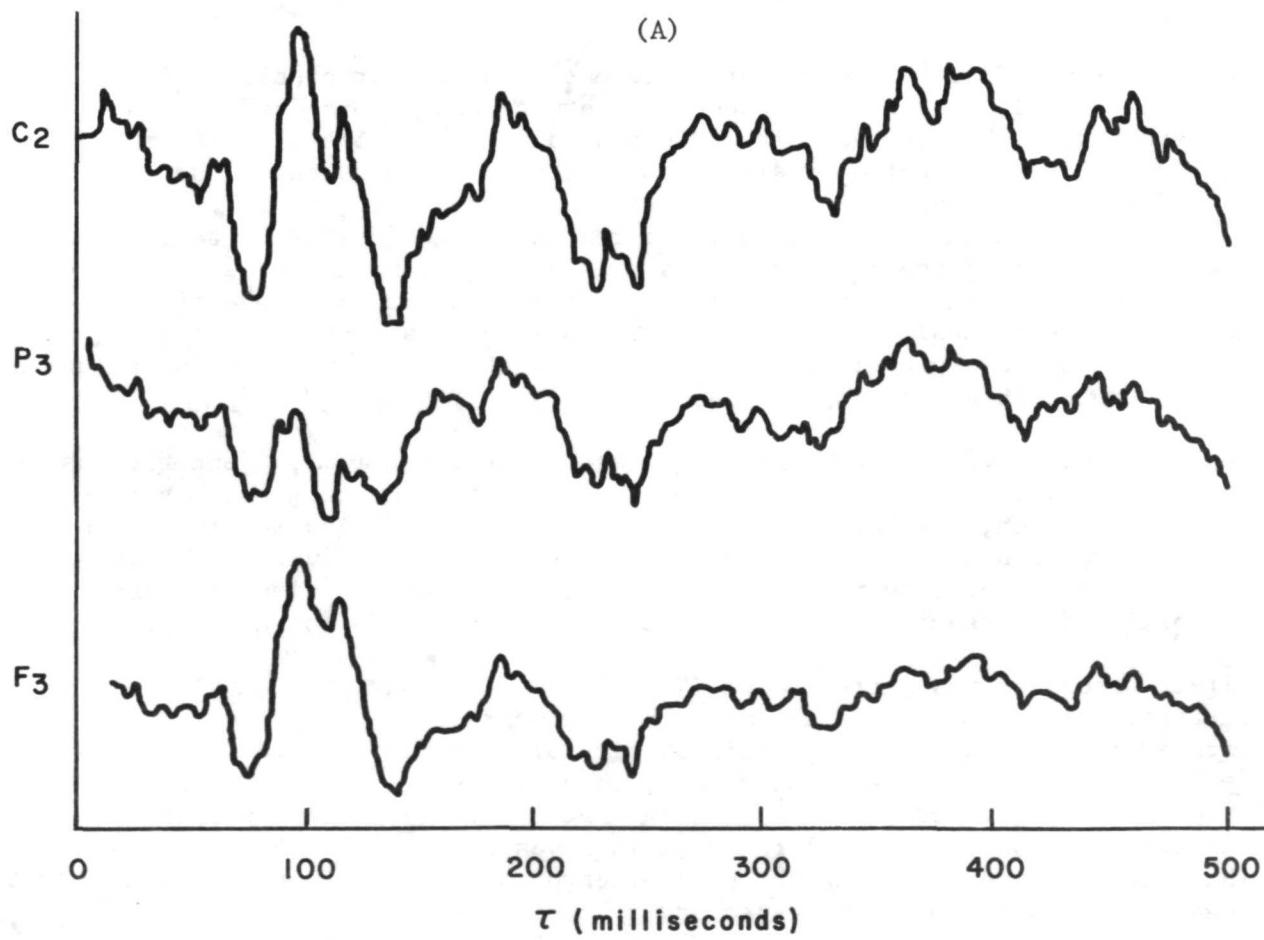
Severely mentally retarded children present a particular problem. It is desired to employ these techniques to determine neurologic dysfunction in these children, but conventional EEG techniques are impossible with these children. They present very significant problems in handling. They are very difficult to engage in any long-term activity; e.g., it is virtually impossible to persuade such a child to remain seated for the 10 to 15 minutes required to attach the EEG electrodes. In addition, hostile reactions are not infrequent in which the child will reach up and rip an electrode off while another is being applied. As a result, a simpler means of obtaining EEG data is required--specifically, a technique that will permit the installation of electrodes in a very rapid fashion.

An EEG helmet developed by NASA in the astronaut program was identified as potentially useful in this application. One of the EEG helmets, a three-electrode design, was borrowed from the NASA Biomedical Applications Team at SwRI, which has been modifying the helmet design for civilian biomedical applications. The researcher tested the helmet at Emory University Regional Rehabilitation Research and Training Center using the following procedure.

First, a subject was fitted using EKG solution and conventional silver dish electrodes mounted with collodion. Three electrodes were employed, one each at the C₂, P₃, and F₃ positions, with all signals referred to the left ear. Visually evoked potentials, obtained by using a strobe lamp, were recorded for 200 stimuli. The data were averaged by computer and the average evoked potential for each lead was plotted (See Figure B-6A). The test was repeated using the same electrodes in order to obtain some idea of the variation to be expected with this subject. These data are plotted in Figure B-6B.

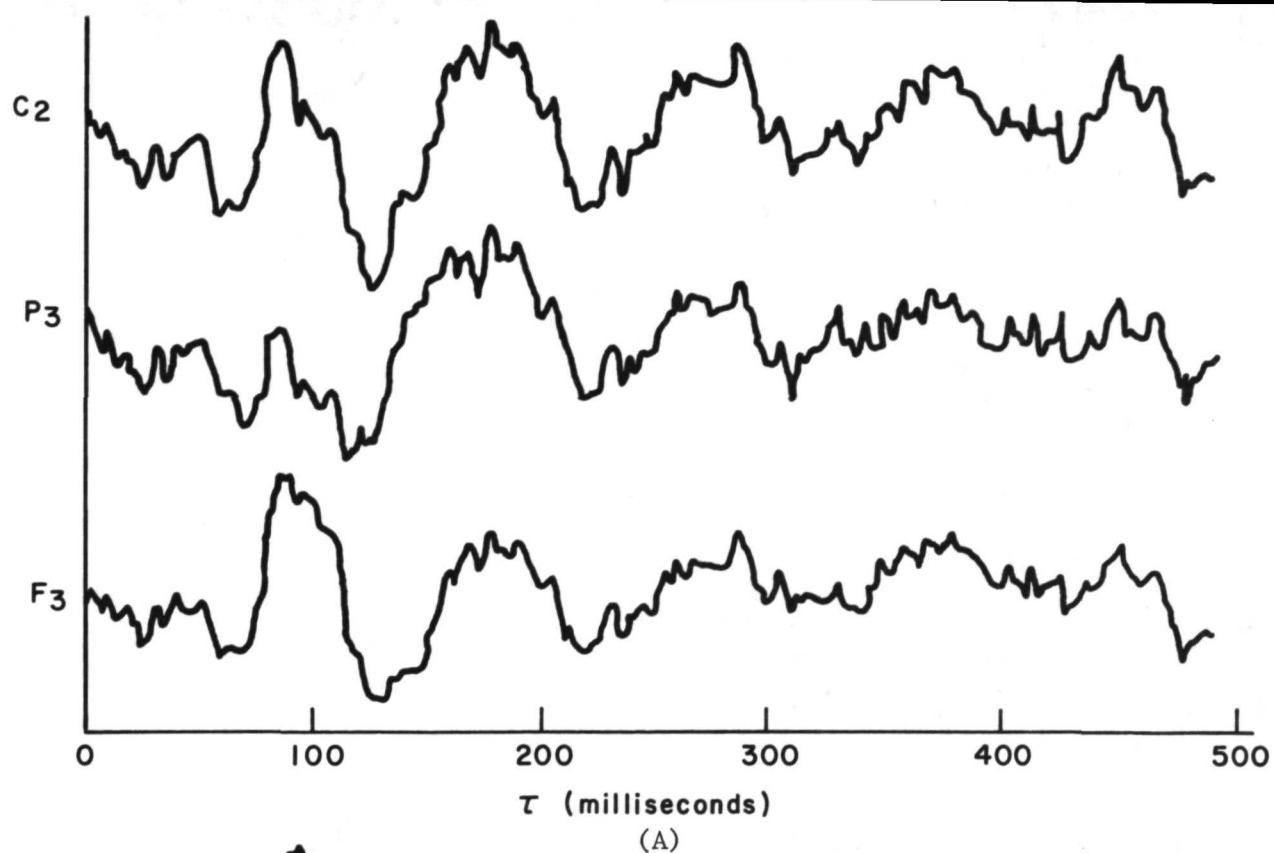


(A)

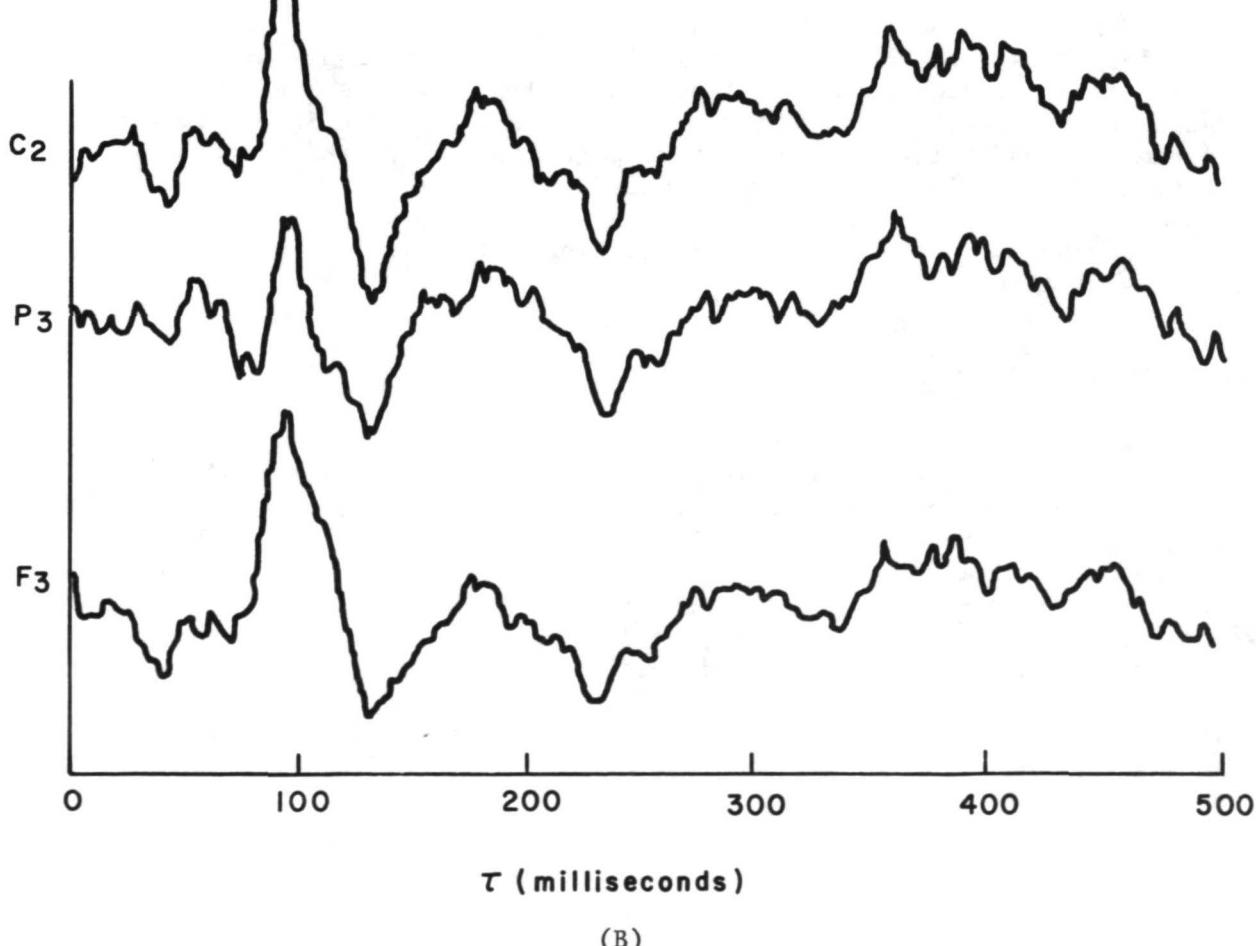


(B)

Figure B-6. Visually Evoked Response with EEG Helmet (Average of 200 Trials).



(A)



(B)

Figure B-7. Visually Evoked Response with Conventional Electrodes
(Average of 200 Trials).

The conventional electrodes were removed, the skull carefully cleaned to remove collodion, and the helmet was fitted. Electrode placement was adjusted to obtain, as nearly as possible, the same locations as in the previous trials. The subject was then stimulated using the strobe for 200 flashes as before, and the averaged EEG curve for each lead was plotted (See Figure 7A). Since the electrode conductor in the helmet electrode is actually saline solution, it was decided to inject an excess amount of saline (as might accidentally occur occasionally). Saline was injected until it ran down the sides of the patient's head and the tests were repeated. The data from this test are shown in Figure B-7B. It can be clearly seen that excess saline has little observable effect on the records. It was concluded from these tests that (1) the helmet technique provides EEG records that are of comparable quality to those using conventional techniques, and (2) the helmet method is faster and easier than conventional techniques if more than one electrode is involved. Further, it would be significantly faster and easier for the application of seven electrodes on children as is desired by the researcher.

The EEG helmet will definitely solve the researcher's problem; however, during the time period in which the EEG helmet trial was arranged, another technique developed under a NASA contract at UCLS was identified. This unit employs techniques basically similar to those used in the EEG helmet. In the UCLA-developed unit, the cap is made from a stretchable polymer and is donned much like a bathing cap. Because it stretches, electrode adjustment to fit each child's skull is not required. It is significantly lighter in weight than the helmet, which is a distinct advantage with children. One further advantage, at least in a screening program such as that planned by the researcher, is that the electrode positions and spacings remain relatively constant.

The researcher is designing and constructing a soft cap EEG helmet at the present time.

PROBLEM MISC-24 *Metal pH Electrodes*

Shock, a complex self-compounding process that is often encountered, is initiated by many causes. Regardless of the cause, the progression is similar in all cases. Protective mechanisms are set in action that greatly restrict blood flow through peripheral capillary beds. These beds rapidly become hypoxic (lack of oxygen) with a decrease in pH. If untreated, the changes lead to various stages of progressive deterioration from which recovery becomes increasingly difficult. A stage is reached at which treatment is ineffective and death is inevitable.

Early warning of the onset of shock greatly improves the prognosis. The problem originator believes that monitoring of the peripheral pH change can provide this early warning. Unfortunately, commercially available implantable electrodes do not meet the rigors of patient monitoring.

A search of aerospace literature reveals no applicable technology. However, BATeam personnel identified a recently initiated NASA implantable pH electrode development program, and contact was established between the development personnel and the problem originator. In addition, commercially available technology was identified to the problem originator, and he has used this technology to develop a prototype electrode which is now being evaluated.

PROBLEM UNC-66 *Determining Tissue Perfusion Adequacy*

Patients suffering from vascular disorders often encounter pain when attempting a routine physical activity, such as walking. These symptoms may result from inadequate tissue perfusion. If uncorrected, the prognosis is usually one of progressive immobilization combined with irreversible damage to the affected tissue.

If the cause is vascular blockage, in most cases it can be accurately located and removed or bypassed. This restores the blood flow but not necessarily the tissue perfusion. Physiological control systems allow large portions of the blood-flow increase to bypass the nutritional capillary beds. In addition, the tissue deterioration could be too extensive to permit perfusion. In either case, additional corrective action is necessary, preferably before the ongoing surgery is terminated. Unfortunately, the physician does not now have a method for quickly evaluating the adequacy of tissue perfusion. Such a method would save the patient the trauma and expense of additional surgery. It would also provide more effective treatment.

One possible indicator of increasing stages of tissue deterioration would be the levels of the proteolytic enzymes that are present in the affected tissue. A joint investigative program with Ames Research Center using the proteolytic enzyme assay is being pursued.

PROBLEM UNC-78 *Platelet Aggregation Detection in Whole Blood*

Platelets are one of the microscopic bodies found in blood. They are disk or platelike structures approximately 2.5 to 3.5 micrometers in diameter, and are present in approximate concentrations of 300,000 platelets per mm³ of whole blood. They play a vital role in the coagulation of blood.

Normally, platelets do not stick to anything or to each other but float freely. However, as an initial step in the clotting process, some mechanism (currently unknown) changes this characteristic. Platelets then adhere to each other forming clumps. The clumps may be only two platelets or a gigantic mass composed of several hundred platelets. This process is known as platelet clumping or platelet aggregation, and, since the process is activated in a number of pathological conditions, it is the subject of intense study.

Currently, to measure the rate and degree of clumping, platelet-rich plasma is prepared by centrifuging whole blood thus eliminating most of the erythrocytes (red cells). Then a device, based on light absorption, is used to measure the rate and degree of aggregation. This procedure is undesirable since it takes time and is in itself suspected of producing a certain amount of clumping. It is therefore desirable to be able to detect the onset and measure the rate and degree of aggregation in samples of whole blood.

The presence of red cells and white cells makes this a very difficult problem. Red cells are bi-concave in shape, 8 to 9 micrometers in diameter, and are present in concentrations of several million per mm³ of whole blood. White cells are spherical in shape, 6 to 15 micrometers in diameter, and present in concentrations of 6 to 8 thousand per mm³ of whole blood.

It has been noted that, just prior to aggregation, platelets become spherical and are covered with small pseudopod-type projections.

A problem statement is being prepared.